

Determination of Human Exposure to Lead and Cadmium: A WHO/UNEP Pilot Study

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Abstract

In Stockholm, methods for measuring exposure to lead and cadmium from air, food and beverages were studied in 1988 in a group of 15 non-smoking women, as part of the WHO/UNEP HEAL programme. Airborne particles in the breathing zone air (24-hour samples), duplicate diets (24-hour samples), and faeces (all the stools produced) were collected during 7 consecutive days. Blood was sampled before and immediately after the study period. The results confirmed the need for personal monitoring in the assessment of human exposure to lead and cadmium via air and food. There is need for suitable equipment for 24-hour personal air monitoring. On average, dietary lead ($26 \mu\text{g day}^{-1}$, SD 7.9) contributed more than 80% of the total lead uptake, while dietary cadmium ($8.5 \mu\text{g day}^{-1}$, SD 2.1) contributed about 99% of the total cadmium uptake. Occasionally consumed foodstuffs with high levels of lead or cadmium seemed to be responsible for a large part of the total weekly intake of lead and cadmium. Fecal lead and cadmium were found to be useful indicators of the total amounts of these metals ingested. Due to the large day-to-day variation observed in the dietary intake of lead and cadmium, the sampling period for duplicate diets and faeces should be at least 5–6 days.

Introduction

The World Health Organization (WHO) and the United Nations Environment Programme (UNEP) are coordinating an international exposure assessment effort – the Human Exposure Assessment Locations (HEAL) programme (UNEP/WHO, 1985, 1986). In one of the first projects methods for monitoring exposure to lead and cadmium from air, food and beverages were studied during one week in small groups of non-smoking women, 23–53 years of age, in Beijing, Stockholm, Yokohama and Zagreb. The main objective was to develop and test methods for monitoring personal exposure to lead and cadmium, including methods for quality assurance. A report of the international studies has recently been published (Vahter and Slorach, 1990). The present report briefly describes the methods used in the determination of human exposure to lead and cadmium. The evaluation is based mainly on the exposure study carried out in Sweden (Vahter *et al.*, 1991).

Materials and Methods

Samples of airborne particles, duplicate diets, faeces and blood were collected in a group of 15 non-smoking women, 27–46 years of age, in Stockholm in February–March 1988. Questionnaires concerning personal data were completed by each woman. All containers and other equipment used for sampling, storage and sample preparation were checked to ensure that they did not release lead or cadmium.

Total suspended particles in the breathing zone of each subject were sampled during 7 consecutive 24-hour periods

using low-volume personal air samplers (Casella T 13350), with a flow rate of 2 L min^{-1} , and 37 mm membrane filters with $0.45 \mu\text{m}$ pore size.

To determine ingested lead and cadmium, duplicates of all foods and beverages, including drinking water, but not certain medicines or chewing gum, were collected as 24-hour samples during the 7 consecutive days. Daily food records were completed by each participant. The subjects did not have to weigh each food item consumed, since it was feared that the extra work and inconvenience this involved would influence their food intake. Consumption of canned food, which may contain much more lead than the corresponding fresh foods (Slorach and Jorhem, 1982), and the approximate volume of beverages were recorded. The women had daily meetings with the study supervisor. Any change in food consumption habits due to sampling procedures or any foods ingested, but not duplicated, were noted in a food record follow-up questionnaire on a day-to-day basis.

All faeces corresponding to the food and beverages ingested during the 7 days were collected. In order to indicate the faeces to be collected, a colored marker (carmines red) was ingested at the beginning and at the end of the duplicate diet collection period. The first colored stool, representing the first duplicate diet collected, was collected. The second colored stool, representing food and beverages ingested after the duplicate diet collection period, was not included.

Blood (10 mL venous blood) was collected at the beginning of and immediately after the study period of 7 days, for evaluation of the total exposure to lead and cadmium.

Quality control (QC) samples (both internal QC samples

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with concentrations of lead and cadmium known to the analyst, and external QC samples with concentrations not known to the analyst) of all the media involved were analyzed together with the monitoring samples. The preparation of the QC samples (spiked bovine blood, freeze-dried human faeces, spiked membrane filters, house dust, and freeze-dried simulated human diets) has been described by Lind *et al.* (1988), and Jorhem and Slorach (1988). The analytical performance evaluation involved the analysis of sets of 6–12 QC samples and evaluation of the analytical results using linear regression analysis (Vahter and Friberg, 1988). For acceptance, the regression line of the reported versus the reference values had to fall inside a given interval. The ranges of concentrations of lead and cadmium in the QC samples were chosen to cover the ranges of concentrations expected to be found in the monitoring samples collected in the various participating countries. The analytical procedures have been described elsewhere (Vahter and Slorach, 1990).

Results and Discussion

The results of the quality control analyses carried out together with the analyses of the monitoring samples were in good agreement with the reference values. However, some of the monitoring samples contained less lead and cadmium than expected and the lowest concentrations were not always covered by the range of QC samples (Vahter *et al.*, 1991).

The concentrations of lead in blood of the 15 women ranged from 15 to 44 $\mu\text{g Pb L}^{-1}$ (median 28, mean 29, SD 8.3). The concentrations of cadmium in blood ranged from 0.1 to 0.8 $\mu\text{g Cd L}^{-1}$ (median 0.3, mean 0.3, SD 0.16).

The main sampling problems were associated with the personal 24-hour monitoring of airborne lead and cadmium. Since the commercially available personal air monitors are designed for occupational exposure monitoring of 8-hour periods it was necessary to recharge the batteries every 6–8 hour. When the subject was not moving, the pump was connected to the mains. Furthermore, the pumps were noisy. It was concluded that there is a need to develop better equipment for 24-hour personal air sampling.

The concentrations of lead and cadmium in breathing zone air were very low during the study week, probably partly because the women spent about 90% of their time indoors. The weekly average concentrations of lead in breathing zone air ranged from 42 to 94 ng m^{-3} (mean 64, SD 14). The concentrations of cadmium ranged from 0.5 to 1.1 ng m^{-3} (mean 0.8, SD 0.16). On average, airborne cadmium contributed about 1% to the total uptake of cadmium, while airborne lead contributed about 15% to the total uptake of lead. In a full-scale study, on a representative sample of the general population in Stockholm, it would not be essential to carry out personal air monitoring of cadmium. Personal monitoring of exposure to airborne lead might be useful in areas with heavy traffic during seasons when people spend more time outdoors.

A total of 105 daily duplicate diets were collected. The content of lead and cadmium ranged from 4.4 to 130 $\mu\text{g Pb}$ per diet and 1.8 to 56 $\mu\text{g Cd}$ per diet. The average daily dietary intake of lead during the 7 day period for the 15 subjects was 26 μg (SD 7.9, range 13–40). The corresponding cadmium intake was 8.5 μg (SD 2.1, range 5.7–14). On average, dietary lead contributed more than 80% of the total lead uptake, while

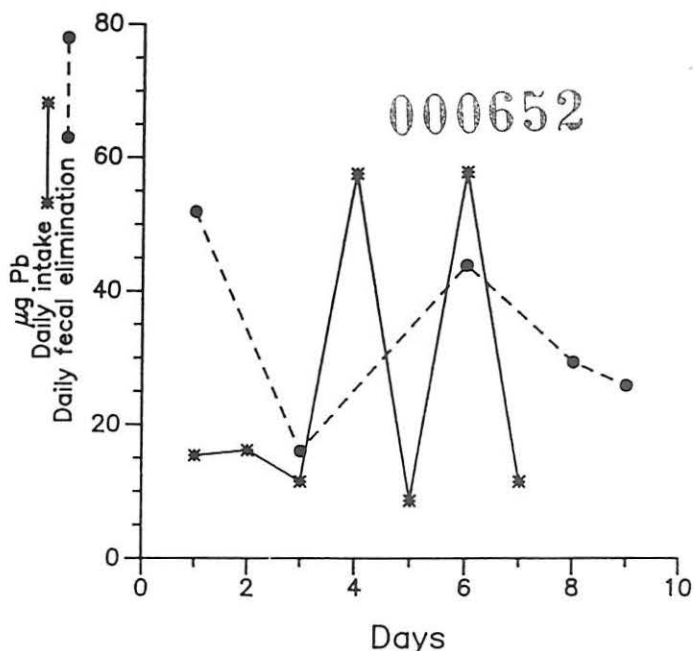


Figure 1 Example of day-to-day variations in dietary intake and faecal elimination of lead by one subject during one week.

dietary cadmium contributed about 99% of the total cadmium uptake.

There were large day-to-day variations in the dietary intakes of lead and cadmium. One daily diet could contribute more than 50% of the total weekly intake of lead or cadmium. This indicates that certain occasionally consumed foods were responsible for a large part of the total dietary intakes of these metals. Evaluation of the food records made it possible to associate some of the observed high levels of lead and cadmium in the 24-hour duplicate diets with certain foods, for instance lead in canned food and wine, and cadmium in sea food (Vahter *et al.*, 1990).

The large day-to-day variations in the dietary intakes of lead and cadmium has to be considered when choosing the method for measuring dietary intake. The duplicate diet method is probably more suitable for measuring dietary intakes of lead and cadmium than methods based on the analysis of individual foods combined with food consumption data. However, it should be noted that the food intake may decrease, and that the food consumption pattern may change due to the duplicate diet sampling. In the Swedish study group there was no indication of markedly decreased food intake due to the duplicate diet sampling. The daily intakes of foods and beverages (range 307–477 g dry weight) did not indicate a low food intake. According to the food record follow-up questionnaires, the women had collected essentially everything ingested, and only minor changes in dietary habits were noted, for instance eating half an apple instead of a whole one because the subject only had one apple and half of it had to be put in the duplicate diet container.

The large day-to-day variations in dietary intake have to be considered also when deciding on the number of days and persons to be studied. In order to evaluate the number of study days required for reliable estimates of dietary intake, the average daily intakes of lead and cadmium were calculated for 2, 3, 4, 5 and 6 days of sampling for each person, and related

to the 7-day average. With 3 days of sampling the average daily intake of lead and cadmium was about 90% of the 7-day average, indicating a reasonably good estimate on a group basis. However, the variation between individuals was large (range 28–149% for lead, and 48–112% for cadmium). With 6 days of sampling the variation decreased for both lead (range 84–115%), and cadmium (range 89–112%). Thus, it was concluded that six days were required to obtain reasonably good estimates on an individual level (Vahter *et al.*, 1991). Longer periods of duplicate diet collection may influence the food consumption pattern.

All the women in the Swedish study group reported complete faeces collection. The faecal elimination of lead and cadmium was calculated from the total amounts of lead and cadmium eliminated during the sampling period, and compared with the metal contents of the duplicate diets collected during the 7 days. The total faecal elimination, expressed as a percentage of the dietary intake, was 104% (range 72–158%) for lead and 113% (range 74–148%) for cadmium. It can be estimated that only a minor part (about 5%) of the lead and cadmium in faeces originated from the faecal excretion of endogenous lead and cadmium (Chamberlain, 1985; Elinder, 1985; Nordberg *et al.*, 1985). A reason for high recoveries may be that the faeces collected did not correspond exactly to the food collected. Some of the first colored faeces samples collected contained 2–9 times as much lead or cadmium as the corresponding duplicate diet (Figure 1). Since the duplicate diet collection started at 3 pm, at which time also the colored marker was ingested, a high dietary lead or cadmium intake earlier that day or the day before may have influenced the first colored faeces samples.

When the first colored faeces samples with metal contents exceeding the corresponding first duplicate diet by 2–9 times were excluded, the average faecal elimination of lead, adjusted for excretion of endogenous lead, was 85% (range 59–121%) of the dietary content, which is consistent with the reported 10–20% average gastrointestinal absorption of lead in adults (Chamberlain, 1985; Rosen, 1985; Tsuchiya, 1986). The corresponding figure for cadmium was 97% (range 66–144%), which is consistent with the 5% average gastrointestinal absorption of cadmium (Friberg *et al.*, 1986). However, even after the adjustments the faecal elimination of lead and cadmium in some women exceeded the amounts found in the duplicate diets, indicating incomplete duplicate diet collection or other sources of lead and cadmium besides the diet. It could be estimated from the air filter samples that the contribution to faecal lead and cadmium from particles inhaled, cleared from the lungs and swallowed, was negligible (Vahter *et al.*, 1991). Other sources of peroral lead, such as toothpaste, lipstick *etc.* were not investigated in the Swedish study.

Faecal lead and cadmium may be used as indicators of the total amounts of these metals ingested. Faeces collection does not influence the food intake or the food consumption pattern. It is considerably cheaper than the duplicate diet technique and in many cases less inconvenient for the subjects involved. The first colored stools appeared between days 1 and 5, indicating large variations in the gastrointestinal transit time. The average daily faecal elimination of lead (24 µg, SD 9.7, range among subjects 10–41 µg) and cadmium (8.9 µg, SD 2.0, range among subjects 5.5–12 µg) was calculated by dividing the total faecal metal content during days 3 to 8 of the test period (for one

subject days 5 to 10) by 6. In order to evaluate the number of study days required for reliable estimates of faecal elimination, the average daily faecal elimination calculated for 2, 3, 4 and 5 days for each person were related to the 6-day average. The interindividual variations decreased with the number of days studied for both lead and cadmium. With 4 days of sampling a reasonably good estimate on a group basis was achieved, the average faecal elimination of lead was about 90% of the 6-day average, but the range was still wide (23–130%). With 5 days of sampling the faecal lead elimination in percent of the 6-day mean ranged from 71 to 115%. The data for cadmium were similar. Thus, it was concluded that at least five days were required to obtain reasonably good estimates on an individual level (Vahter *et al.*, 1991).

Conclusions

The results confirm the need for personal monitoring in the assessment of human exposure to lead and cadmium via air and food. There is a need to develop better equipment for 24-hour personal air sampling.

The duplicate diet collection period should be at least 6 days in order to obtain reasonably good estimates of daily dietary intake of lead and cadmium. The diet was the major source of exposure to both lead and cadmium. Occasionally consumed foods seemed to be responsible for a large part of the total intake of lead and cadmium.

On a group basis, faecal lead and cadmium may be used for validation of the duplicate diet collection efficiency. Faecal lead and cadmium were found to be useful indicators of the total amounts of these metals ingested. Due to the large day-to-day variations in dietary intake of lead and cadmium, and variations in the gastrointestinal transit time, the faeces sampling period should be at least 5 days.

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Personal monitoring of lead and cadmium exposure — a Swedish study with special reference to methodological aspects

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VAHTER M, BERGLUND M, LIND B, JORHEM L, SLORACH S, FRIBERG L. Personal monitoring of lead and cadmium exposure — a Swedish study with special reference to methodological aspects. *Scand J Work Environ Health* 1991;17:65-74. Methods for determining personal exposure to lead and cadmium were tested in Stockholm in 1988. Lead and cadmium in breathing-zone air, 24-h duplicate diets, and feces of 15 nonsmoking women (27-46 years of age) were studied. Blood was collected at the beginning of and immediately after the test period (seven consecutive days). An extensive quality assurance program was included. Most technical problems were encountered in the 24-h collection of airborne particles. The pumps were noisy, and the batteries had to be recharged every 6-8 h. The lead and cadmium levels in feces were found to be useful indicators of the total ingested amounts of these metals. Because of the large day-to-day variation in the dietary intake of lead and cadmium, the sampling period for duplicate diets and feces should be at least 5-6 d.

Key terms: air, blood, duplicate diets, dust, exposure, feces, methods, quality control.

Lead (Pb) and cadmium (Cd) may be found in work environments, ambient air, dust, drinking water, food, and tobacco smoke. For both metals the difference between the average human exposure levels and the exposure levels at which the first signs of adverse health effects can be seen is very small. Accurate estimates of human exposure to environmental pollutants are of vital importance for the assessment of the risks these pollutants pose and for the design and implementation of efficient control strategies. The World Health Organization (WHO) and the United Nations Environment Programme (UNEP) are coordinating an international exposure assessment effort — the Human Exposure Assessment Location (HEAL) program (1, 2). Initially, methods for monitoring exposure to lead, cadmium, chlorinated hydrocarbons, and nitrogen dioxide, including methods for quality assurance, were developed and tested on small groups of selected individuals. Measurements of personal exposure to lead and cadmium from air, food, and beverages were carried out on small groups of nonsmoking women in Beijing, Stockholm, Yokohama, and Zagreb. A review of the studies has recently been published by WHO and UNEP (3). Our report gives a detailed evaluation

of the methods used in the determination of human exposure to lead and cadmium in Stockholm.

Material and methods

Study design and sampling

Exposure monitoring of lead and cadmium, involving 15 nonsmoking women, 27-46 years of age, and not occupationally exposed to lead or cadmium, was carried out in February and March of 1988. Personal exposure via air, food, and beverages was measured during seven consecutive 24-h periods. Each period started in the afternoon at 1500. The nonsmoking women working in three departments of the Karolinska Institute in Stockholm were asked to join the study. All but one of 18 women agreed to participate. Before the beginning of the measurements the women were informed about the aims of the study, the sampling procedures to be used, and how to avoid contamination of the samples. Questionnaires concerning personal data, life-style factors, health status, home address, occupation, and so forth were completed by each participant. In order to check that all the samples were collected and labeled properly and that the questionnaires were completed, the study supervisor had daily meetings with the subjects, and any problems were discussed.

Lead and cadmium in blood were determined for the evaluation of the total exposure (4-6). Blood samples (10 ml venous blood) were collected at the beginning of and immediately after the test period (days 1 and 8) in evacuated blood collecting tubes (Venoject,

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VT-100H, Terumo Corporation, Tokyo) containing heparin as an anticoagulant. The blood was transferred to 5-ml polyethylene tubes and stored deep-frozen until the analysis.

The total amount of suspended airborne particulates (24-h samples) in the breathing zone of each subject was sampled during the whole test period of seven consecutive days. Low-volume personal air samplers (T 13350 Casella pump AFC 123, equipped with alternating current adapters) with a flow rate of 2 l/min were used. The Casella pump AFC 123 was chosen from six different personal air-monitoring devices on the Swedish market because of the relatively low noise level, low weight (460 g), the built-in low battery shutdown device, a flow rate at 2 l/min kept within $\pm 5\%$, and a fairly low price. The filter holders were equipped with 37-mm membrane filters (Millipore HAWP 03700) with a 0.45- μm pore size. The pump was carried at all times as the subjects moved around outdoors and indoors. During most of the time spent in one and the same room the pump was connected to an electrical outlet to recharge the batteries. In a test of sampling efficiency in relation to the pore size of the filters, airborne particles were simultaneously collected on four occasions (2 d indoors and 2 d outdoors) with 0.45- and 0.8- μm pore size filters.

For the evaluation of the dietary intake of lead and cadmium, duplicate portions of all foods and beverages, including drinking water, but not certain medicines and chewing gum, consumed during the entire study period were collected as 24-h samples. Duplicate portions of everything ingested during each 24-h period, starting in the afternoon at 1500, were collected in one and the same container and stored deep-frozen until the analysis. Food records were kept by each participant so that the relation between high intakes of lead and/or cadmium and the consumption of certain foods could be studied. The consumption of canned foods was recorded, since it is known that foods packed in lead-soldered cans may contain much more lead than the corresponding fresh foods (7). The subjects were not asked to record the weight of each food item consumed, since it was feared that the extra work and inconvenience involved would influence the food consumption pattern. However, they were asked to record the approximate volume of beverages consumed. In the follow-up questionnaires on the recording of foods, information was sought on foods ingested but not collected as a duplicate portion and any changes in food consumption habits due to the sampling procedure.

In adults the gastrointestinal absorption of lead and cadmium is low, about 5–20% on the average (8–11). Therefore, the fecal content of lead and cadmium may be used as an indicator of the amounts of lead and cadmium ingested. Provided that there are no other sources of ingested lead and cadmium, fecal lead and cadmium may be used for validating the results of the duplicate diet study. All feces corresponding to

the food and beverages ingested during the entire study period were collected. Since the gastrointestinal transit time varies greatly (12), a colored marker (carmine red, checked for metal content) was ingested at the beginning and at the end of the food sampling period in order to indicate the first and last stools to be collected. The first colored stool, but not the second, was collected. The feces were collected in specially designed metal-free plastic bags, weighed, and stored deep-frozen until the analysis.

Analytical procedures

All utensils were washed with 10% nitric acid and rinsed several times with deionized water before use. Standards were prepared from stock standards (British Drug Houses, United Kingdom) containing 1000 mg/l of the metals as nitrate salts.

Blood samples were analyzed according to Stoeppler et al (13) and Stoeppler & Brandt (14), with certain modifications (15, 16). An 0.3-ml sample was deproteinized by the addition of 0.5 ml of 0.8 M nitric acid. The concentrations of lead and cadmium were determined with the use of graphite furnace atomic absorption spectrophotometry (GFAAS) with background correction and peak area evaluation (Perkin Elmer models 373 and 5000 Zeeman with HGA—500, autosampler AS—40, recorder 056 and computer Epsom Hx20 or Perkin Elmer 7500). Standard graphite tubes were used for the determination of lead and l'Vov's platform in a pyrolytical graphite tube for the determination of cadmium.

Air filters were digested in 2 ml of concentrated nitric acid/perchloric acid (1:1) at 100°C for 20 min in glass beakers. After dilution to 10 ml with deionized water, the solutions were analyzed by GFAAS with background correction after a further 1:1 dilution with deionized water. Quality-control samples of dust were analyzed with the same method, but the concentrations of lead and cadmium were determined by flame atomic absorption spectrometry with background correction.

The diet samples were thawed and each 24-h sample was thoroughly homogenized in a food blender equipped with a titanium knife. Subsamples were weighed in duplicate into platinum crucibles and, after drying, ashed at 450°C in a time/temperature programmable furnace (Carbolite, Food Ashing, United Kingdom). When free from visible carbon particles, the ash was dissolved in 20 ml of 0.1 M nitric acid (17). Lead and cadmium were determined by GFAAS in a Perkin-Elmer 3030/HGA—500 with a deuterium background correction system, autosampler AS—40 and printer PR—100. All of the determinations were made by the standard addition technique. The energy content of each duplicate diet was determined by standard methods (18).

The frozen feces samples were thawed, dried at 105°C to constant weight, homogenized by grinding in liquid nitrogen with a ring mill (Shatterbox, model

8500, Spex Ind, United States) and freeze-dried (Edwards Modulyo EF4, United States). Duplicates of 2.4 g of the dried sample (corresponding to about 10 g of wet weight) were dry-ashed at 470°C overnight in a time/temperature programmable muffle furnace (Carbolite, Food Ashing). The ash was dissolved in 15 ml of 1 M nitric acid. Empty crucibles treated as those with samples were used as blanks. Standards were made in 1 M nitric acid. Flame atomic absorption spectrophotometry with deuterium background correction was used for the determination of lead and cadmium (19, 20).

The analytical quality control was based on the program developed in the UNEP/WHO biological monitoring project for lead and cadmium (21–23). The analytical performance evaluation involved the analysis of sets of quality-control samples and an evaluation of the results with linear regression analysis (24). In general, 8–12 external quality-control samples, the metal concentrations of which were not known to the analyst, were analyzed together with the monitoring samples. The quality-control samples consisted of spiked bovine blood, spiked air filters, house dust, freeze-dried simulated human diets, and freeze-dried human feces. The preparation of the quality-control samples has been described by Lind et al (25) and Jorhem & Slorach (26). The range of concentrations of lead and cadmium in the quality-control samples was chosen to cover the whole range of concentrations expected to be found in the monitoring samples collected at the four HEAL sites.

Results

As shown in figures 1 and 2, the results of the quality-control analyses (blood, air filters, dust, diets, and feces), carried out together with the analyses of the monitoring samples, were in good agreement with the quality-control reference values. Many of the monitoring samples contained less lead and cadmium than expected, and sometimes less than the quality-control samples. Four quality-control blood samples for lead and cadmium were within the concentration range of the monitoring samples. Two of the quality-control samples were internal quality-control samples, containing 28 µg Pb/l and 0.3 µg Cd/l (not shown in the figures); the analysis gave 29 and 27 µg Pb/l and 0.3 and 0.4 µg Cd/l, respectively.

The quality-control air filters contained 1.0–28 µg Pb/filter, while the air monitoring samples contained 0.04–0.49 µg Pb/filter. Blank filters analyzed together with the monitoring samples showed less than 0.03 µg Pb/filter (detection limit), and the analysis of internal quality-control filters containing 1.6 (SD 0.04) µg Pb/filter gave 1.6 (SD 0.11) µg Pb/filter, indicating a $y = x$ equation also in the low concentration range. The quality-control air filters for cadmium contained 6–110 ng Cd/filter, and only one quality-control sample was within the concentration range of the monitor-

ing samples (1–7 ng Cd/filter), most of which were close to the detection limit of 1 ng Cd/filter.

All eight quality-control diet samples for lead and four quality-control diet samples for cadmium were within the concentration ranges of the collected duplicate diets when the latter were calculated on a dry weight (dw) basis [21–469 µg Pb/kg (dw) and 4.8–118 µg Cd/kg (dw)]. Three quality-control feces samples for lead, and four for cadmium, were within the concentration ranges of the monitoring samples [0.2–3.3 µg Pb/g (dw) and 0.2–0.8 µg Cd/g (dw)].

The concentrations of lead and cadmium in the blood collected from the 15 women are given in table 1. There was no difference in the blood concentrations of lead and cadmium between days 1 and 8.

We calculated the concentrations of lead and cadmium in the breathing-zone air by dividing the amounts of lead and cadmium on the filters used in the personal air samplers by the volume (in cubic meters) of air filtered during the 24-h sampling periods. The data are given in table 2. On the assumption of a daily respiration volume of 13 m³ (moderate physical activity), it can be estimated that, on the average, 838 (SD 186) ng of lead and 10 (SD 2.2) ng of cadmium were inhaled per day.

The test for sampling efficiency in relation to the pore size of the membrane filter showed 46 and 66 ng Pb/m³ with a 0.45-µm pore size and 50 and 66 ng Pb/m³ with a 0.8-µm pore size for the two outdoor test sites. Corresponding results for the two indoor test sites were 30 and 58 ng Pb/m³ with the 0.45-µm pore size and 38 and 52 ng Pb/m³ with the 0.8-µm pore size.

A total of 105 daily duplicate diets was collected, seven by each woman. The average daily amount of food and beverages collected, as well as the content of lead and cadmium in the 24-h diets, are given in table 3. The average energy content of the daily duplicate diets was 7.8 (SD 1.3, range 5.8–9.7) MJ. Figures 3 and 4 show the distribution of the lead and cadmium content for the 105 duplicate diets. Figure 5 shows a typical example of the day-to-day variation in the dietary intake of lead and cadmium. In order to evaluate the number of test days required for making reliable estimates of the daily intake, we calculated the average daily dietary contents of lead and cadmium also for assumed test periods of 2–6 d (table 4).

All of the women reported complete feces collection. A total of 123 stools was collected and analyzed for lead and cadmium. For four of the subjects, the first red feces appeared during the first day after the ingestion of the carmine red, for eight subjects during the second day, for two subjects during the third day, and for one subject during the fifth day. The number of stools between the colored markers varied between 5 and 12. The dry weight to wet weight ratio for the feces was 0.28 on the average (SD 0.04, range 0.19–0.34). The total amounts of lead and cadmium eliminated during the whole sampling period were calcu-

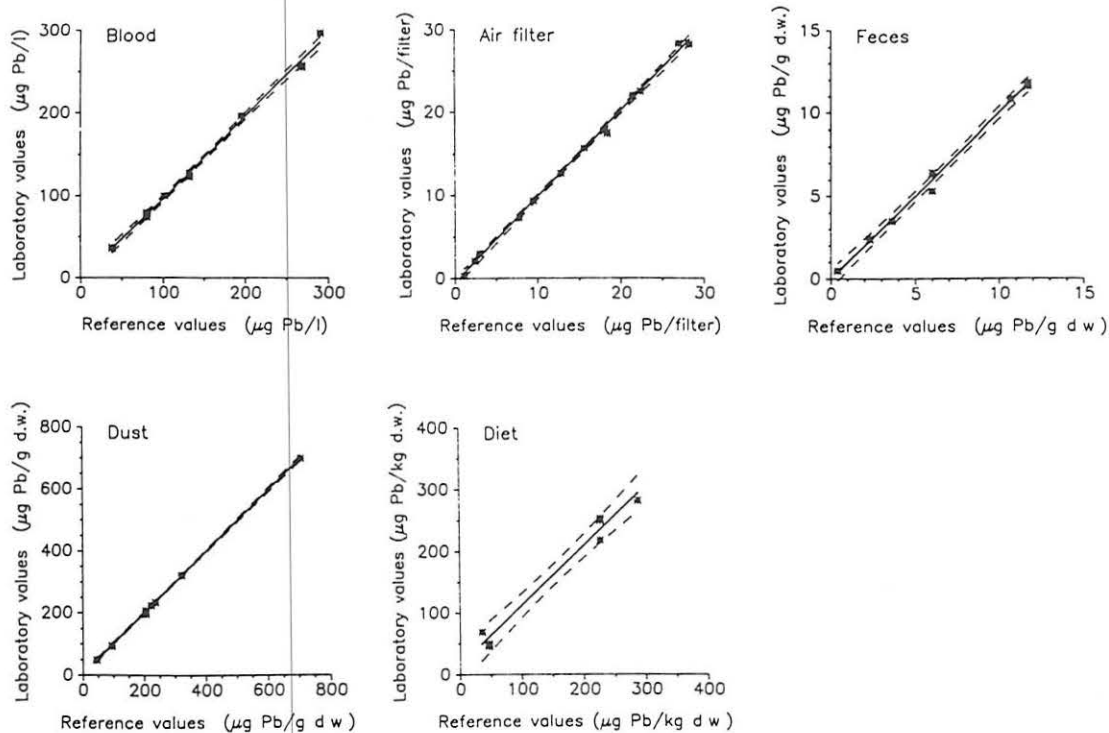


Figure 1. Lead in the quality-control samples (blood, air filter, feces, dust, and diet) analyzed together with the monitoring samples. The 95 % confidence interval is indicated by the broken lines. (dw = dry weight)

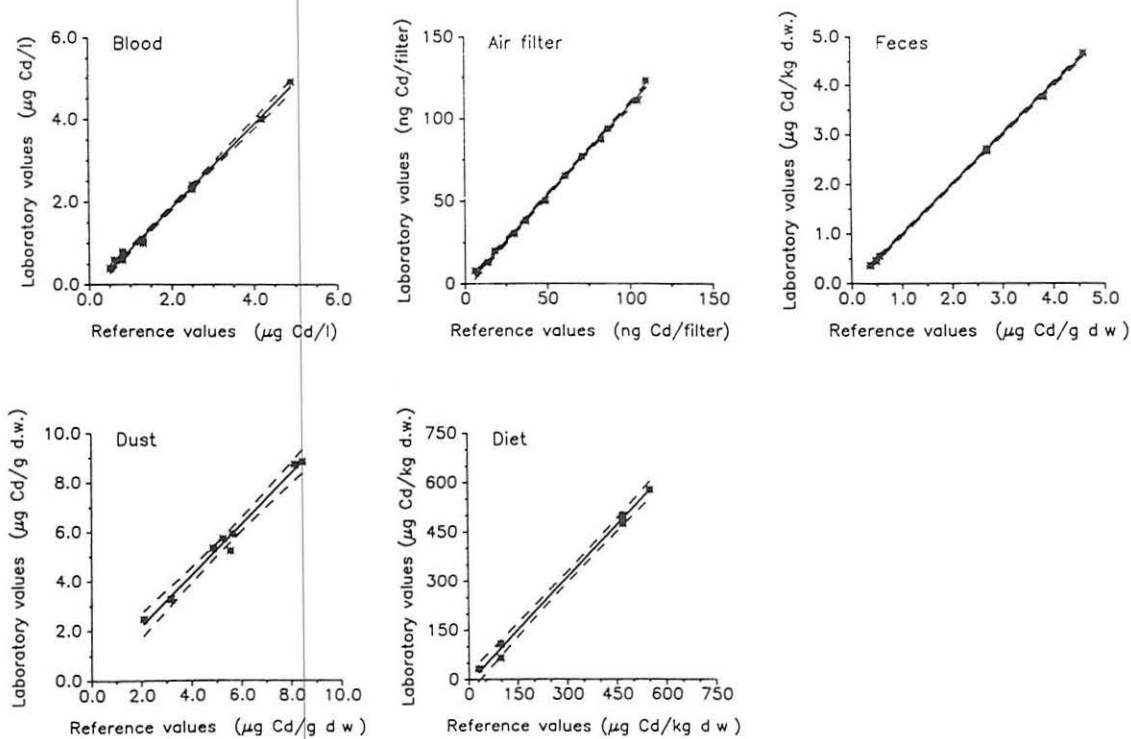


Figure 2. Cadmium in the quality-control samples (blood, air filter, feces, dust, and diet) analyzed together with the monitoring samples. The 95 % confidence interval is indicated by the broken lines. (dw = dry weight)

Table 1. Concentrations of lead (Pb) and cadmium (Cd) in the blood of 15 nonsmoking women.

	Mean	SD	Median	Range
$\mu\text{g Pb/l}$				
Day 1	30	8.1	27	21-44
Day 8	29	8.6	29	15-43
$\mu\text{g Cd/l}$				
Day 1	0.32	0.16	0.33	0.11-0.79
Day 8	0.32	0.17	0.30	0.13-0.86

Table 2. One-week average air concentrations of lead (Pb) and cadmium (Cd) in the breathing zone (personal monitoring) of 15 nonsmoking women.

	Mean	SD	Median	Range	Range ^a
ng Pb/m^3	64	14	66	42-94	15-169
ng Cd/m^3	0.8	0.16	0.8	0.5-1.1	0.4-2.6

^a Range of all 24-h samples.

lated and compared with the metal contents of the duplicate diets collected during the 7 d. The average fecal elimination as a percentage of the dietary intake was 104 (range 72-158) % for lead and about 113 (range 74-148) % for cadmium.

We calculated the average daily stool mass and the daily fecal elimination of lead and cadmium for each woman by dividing the total amounts of feces and fecal

Table 3. One-week average daily intake of food and beverages and dietary intake of lead (Pb) and cadmium (Cd) (duplicate diet contents) for the 15 nonsmoking women.

	Mean	SD	Median	Range
g diet/d				
Wet weight	2342	341	2270	1563-3033
Dry weight	393	52	391	307-477
$\mu\text{g Pb/d}$	26	7.9	26	13-40
$\mu\text{g Cd/d}$	8.5	2.1	8.1	5.7-14

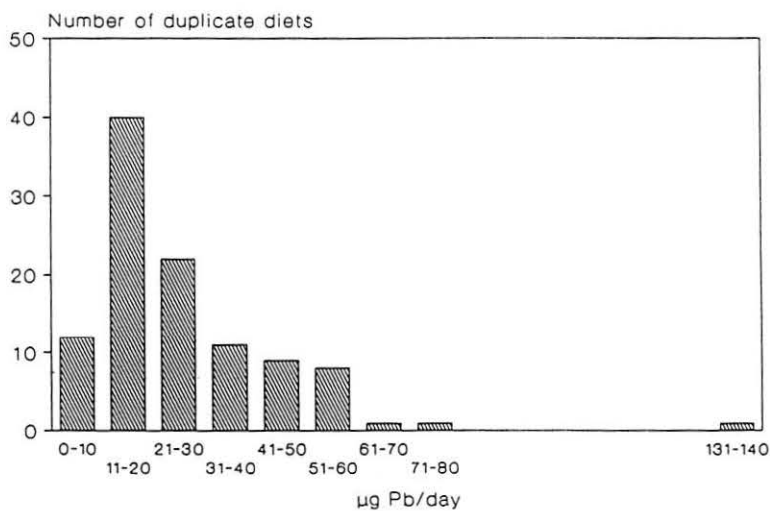


Figure 3. The content of lead in the 105 daily duplicate diets.

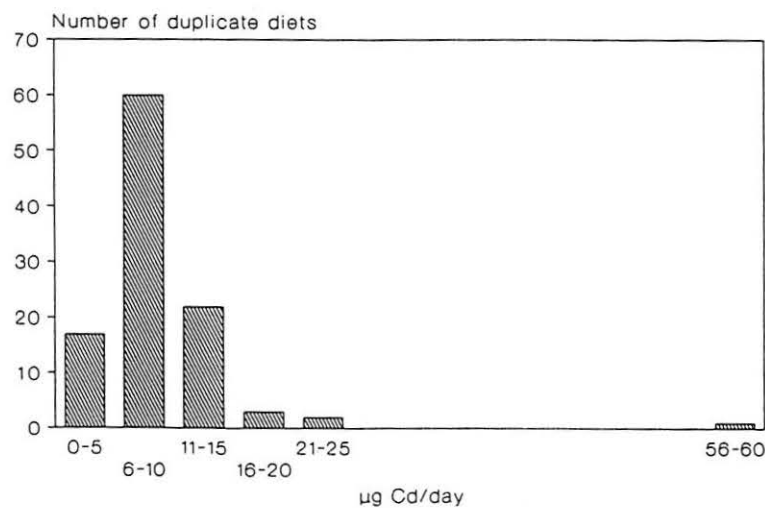


Figure 4. The content of cadmium in the 105 daily duplicate diets.

Table 4. Average daily dietary intake of lead and cadmium in relation to the number of days studied.

Number of days	% of 7-d average					
	Lead			Cadmium		
	Mean	SD	Range	Mean	SD	Range
2	77	27	28-133	81	19	52-118
3	92	31	28-149	88	16	48-112
4	100	23	58-150	103	19	46-129
5	98	19	54-131	99	18	44-121
6	104	8	84-115	102	6	89-112
7	100	.	.	100	.	.

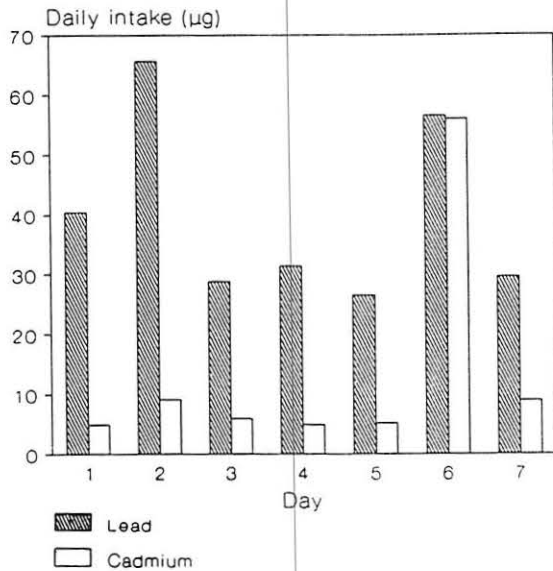


Figure 5. Examples of the day-to-day variation in the dietary intake of lead and cadmium by one subject.

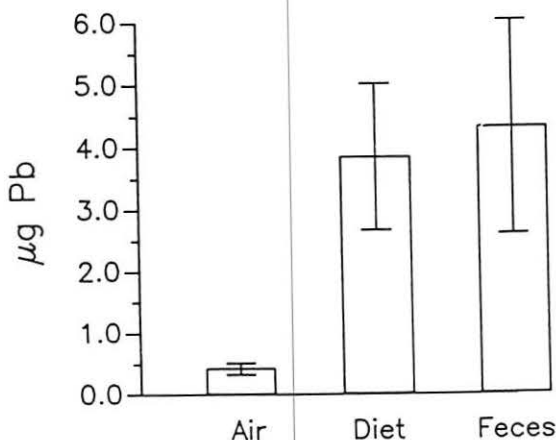


Figure 6. Mean daily absorption of lead estimated from the breathing-zone air levels (on the assumption of 50% absorption in the respiratory tract), duplicate diets, and feces (on the assumption of a gastrointestinal absorption of 15%) of all the subjects. The standard deviations are indicated by the vertical bars.

metal contents during days 3 to 8 of the test period (for one subject days 5 to 10) by 6 (table 5). In order to evaluate the number of study days required for making reliable estimates of the fecal elimination, we calculated the average daily stool mass and average daily fecal elimination of lead in relation to the number of days studied (table 6). Five days were required for obtaining good estimates of both daily stool mass and daily fecal elimination of lead on an individual level.

Table 5. One-week average daily stool mass and fecal elimination of lead (Pb) and cadmium (Cd) from 15 nonsmoking women.

	Mean	SD	Median	Range
g feces/d				
Wet weight	88	45	78	51-232
Dry weight	24	7.5	22	15-44
µg Pb/d	24	9.7	23	10-41
µg Cd/d	8.9	2.0	8.8	5.5-12

Table 6. Average daily stool mass of 15 nonsmoking women and average daily fecal elimination of lead in relation to the number of days studied, starting from day 3 after the ingestion of the marker (for one subject day 5). Figures represent the percentage of average daily fecal elimination of lead during 6 d of feces collection.

Number of days studied	Stool mass (% of 6-d mean)			Fecal lead elimination (% of 6-d mean)		
	Mean	SD	Range	Mean	SD	Range
2 (days 3-4)	80	46	0-141	76	51	0-175
3 (days 3-5)	83	33	7-139	80	38	8-149
4 (days 3-6)	88	31	22-132	86	34	23-130
5 (days 3-7)	94	12	70-107	90	13	71-115
6 (days 3-8)	100	.	.	100	.	.

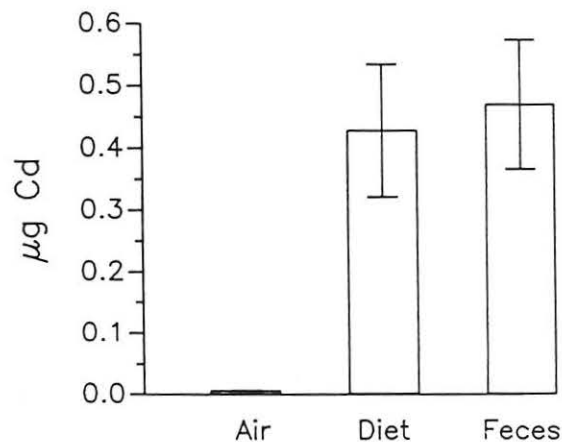


Figure 7. Mean daily absorption of cadmium estimated from the breathing-zone air levels (assuming 50% absorption in the respiratory tract), duplicate diets, and feces (on the assumption of a gastrointestinal absorption of 5%) of all the subjects. The standard deviations are indicated by the vertical bars.

The data for the fecal elimination of cadmium were very similar to those for lead.

The estimated average daily absorption of lead and cadmium, based on the amounts in air, duplicate diets, and feces, is shown in figures 6 and 7.

Discussion

The main objective of the present study was to test exposure monitoring methodologies, and several different sampling techniques were used. The fact that all the women worked at the same place facilitated our evaluation of the problems encountered in the sampling, handling, and storage of the different samples collected. The importance of continuous encouragement throughout the study was emphasized by the subjects. The main sampling problems were associated with the 24-h monitoring of airborne lead and cadmium. The commercially available personal air monitors are designed for occupational exposure monitoring studies with 8-h exposure periods, and it was necessary to recharge the batteries every 6–8 h. Therefore, the pumps had to be connected to an electrical outlet most of the time when the subjects were at home or sitting in their offices. In addition the noise of the operating pumps gave rise to some complaints. Equipment suitable for 24-h personal sampling of the general population needs to be developed. With filters of a larger pore size, giving rise to lower air resistance, the pumps were found to be less noisy. The determination of lead in simultaneously collected samples, with 0.45- and 0.8- μm pore size filters, showed no significant difference in collection efficiency over a 24-h period.

The large day-to-day variation observed in the dietary intakes of lead and cadmium indicates that certain occasionally consumed foodstuffs were responsible for a large part of the total dietary intake of these metals. This fact has to be considered when the method and the number of days and persons to be studied are chosen. The duplicate diet method gives a more precise estimate of the dietary intake than estimates based on the analysis of individual foodstuffs combined with food consumption data. However, it has been reported that the collection of duplicate diets may decrease the food intake and change the food consumption pattern (27). In our study, there was no indication of markedly decreased food consumption due to the sampling. The women indicated only a minor decrease in the amount of food consumed due to the sampling (eg, half a fruit or cake instead of a whole one). One woman had her lunch less frequently at a restaurant. In addition, the amounts of food and beverages ingested, 393 g(dw)/d, on the average, did not indicate a low food intake. Schütz (28) reported an average daily food intake of 313 g(dw) in a study of 33 duplicate diets from 16 Swedish women 68–69 years of age.

According to the follow-up questionnaires on the food records, the women had collected duplicate portions of essentially everything ingested, except chewing gum and certain medicines. Several of the women had more lead and/or cadmium in their feces than in the corresponding duplicate diets, and this result may indicate an error in the duplicate diet collection. However, there may be other explanations for the high fecal elimination of lead and cadmium. Part of these metals in feces originates from the fecal excretion of endogenous lead and cadmium. Chamberlain (8) has estimated the daily clearance of lead in feces to correspond to the amount of lead in 0.05 kg of blood. Thus, in our study, the average fecal excretion of endogenous lead would be about 1.4 $\mu\text{g Pb/d}$ (ie, about 6 % of the average daily fecal elimination). The fecal excretion of endogenous cadmium is about the same as the urinary excretion (29) [ie, about 0.2–0.3 $\mu\text{g/d}$ for nonsmoking Swedish women 30–50 years of age (30)].

A possible reason for the high fecal recoveries after adjustment for the excretion of endogenous lead and cadmium may be that the feces collected did not correspond exactly to the food collected during the study period. Some of the first feces samples collected (with the red marker) contained amounts of lead and/or cadmium greatly exceeding those in the corresponding first day's duplicate diets. Since the duplicate diet collection started at 1500 in the afternoon, at which time the carmine marker was ingested, a high dietary lead and/or cadmium intake earlier that day may have influenced the first colored feces samples. If the first feces samples with metal contents greatly exceeding (2–9 times) those of the corresponding first duplicate diets were excluded, the average fecal elimination adjusted for endogenous excretion, as a percentage of the dietary content, would be 85 (range 59–121) % for lead and 97 (range 66–144) % for cadmium. These figures are consistent with the reported 10–20 % average gastrointestinal absorption of lead in adults (8, 9, 11) and 5 % average gastrointestinal absorption of cadmium (10).

Another possible reason for the high fecal content of the metals in relation to the dietary content may be sources of peroral lead and cadmium other than the diet. It can be estimated that inhaled particles cleared from the lungs and swallowed contributed very little to the fecal lead and cadmium. Even if as much as 90 % of the inhaled lead and cadmium were cleared from the lungs and swallowed, the amount would not contribute more than 0.7 μg of lead and 0.009 μg of cadmium per day to the feces. We did not investigate other sources of peroral lead and cadmium.

As has already been mentioned, fecal lead and cadmium may be used as an indicator of the total ingested amounts of these metals. Feces collection is considerably cheaper than the duplicate diet technique, and in many cases less inconvenient for the subjects involved. Furthermore, feces collection does not influence food

intake and the food consumption pattern. Because of the large day-to-day variations in the dietary intakes of lead and cadmium and variations in the gastrointestinal transit time, the feces sampling period should be as long as possible. In our study, 5 d were required for a reasonably good estimate of the daily fecal elimination. In order that the seasonal variations in metal exposure can be determined, the feces collection must be repeated.

The main problem with fecal lead and cadmium as indicators of exposure is the variation in gastrointestinal absorption between individuals, and possibly also over time for one and the same individual. The gastrointestinal absorption of lead and cadmium is influenced by the nutritional status of the subject, the presence of food in the stomach, and the presence of other metals in the diet (8, 10, 11). Iron deficiency, which is common among fertile women (31), may increase the gastrointestinal absorption of lead and cadmium (32, 33).

The small number of selected subjects studied does not allow an extrapolation of the results to the general population. However, according to the information given in the questionnaires, there is no reason to believe that the selected women differed to any significant extent from nonsmoking women in the general population with regard to their exposure to lead and cadmium. Furthermore, the average blood cadmium level (0.3 $\mu\text{g/l}$) is similar to that reported for nonsmoking women in a previous study (21), and the average blood lead level (30 $\mu\text{g Pb/l}$) is consistent with that (33 $\mu\text{g Pb/l}$) recently reported for children and teenagers in southern Sweden (34, 35). However, the average blood lead level was lower than that (64 $\mu\text{g Pb/l}$, $N=45$) found for nonsmoking women in 1980 (21) and in 1984 (42 $\mu\text{g Pb/l}$, $N=18$) (36). In all these studies blood lead was analyzed with the same procedure with adequate quality control. The decreasing blood lead levels probably reflect a true decrease in the general population's exposure to lead. Legislative measures taken in Sweden in 1981 lowered the maximum permitted level of lead in gasoline from 0.4 to 0.15 g/l, and in 1987 unleaded gasoline was introduced. In 1988 about 30 % of the gasoline used was unleaded. A similar trend of decreasing blood lead levels in parallel to the decreasing lead levels in gasoline has been reported for children in southern Sweden (35, 37). The gradual replacement of food cans with lead-soldered side seams by welded cans or other types of packages (38) may also have contributed to lower blood lead levels.

The levels of lead and cadmium in the breathing-zone air (personal monitoring) were very low, 64 ng Pb/m^3 and 0.8 ng Cd/m^3 . Considerably higher air metal concentrations have been reported for Stockholm in studies using stationary air monitors. In 1987–1988 monthly average air lead levels of 0.4 and 0.7 $\mu\text{g/m}^3$ were found in areas of Stockholm with heavy traffic (39). As to cadmium in air, an annual

mean concentration of 0.9 ng/ m^3 has been reported for rural areas in Sweden and weekly mean concentrations of about 5 ng/ m^3 for Stockholm (40). The most likely explanation for the low air metal levels in our study is that the women under study spent about 90 % of their time indoors. This possibility shows the necessity of personal sampling for the estimation of human exposure to airborne pollutants. On the average, airborne cadmium contributed only about 1 % to the total uptake (absorbed amounts) of cadmium. For lead, the contribution from air was about 10–15 %. In the summer, when people normally spend more of their time outdoors, the contribution from air may be higher.

The diet was found to be the major source of exposure to both lead (average 26 $\mu\text{g Pb/d}$) and cadmium (average 8.5 $\mu\text{g Cd/d}$). Similar daily dietary intakes of lead (27 $\mu\text{g Pb/d}$) and cadmium (10 $\mu\text{g/d}$) were reported in 1983 by Slorach et al (41) on the basis of the analysis of seven prepared daily diets typical for a Swedish adult male. However, the prepared diets did not include canned food or wine, which often contains relatively high levels of lead. In our study a high daily intake of lead was, in many cases, associated with the consumption of these foods. The prepared diets did not include shellfish. In our study the consumption of hand-peeled shrimp, which contain remnants of the hepatopancreas, was associated with a high daily intake of cadmium (18). Further studies are needed to evaluate possible changes in the exposure to lead and cadmium via the diet.

This pilot study made it possible to identify the main problems in the collection and analysis of different types of exposure monitoring samples and to identify major routes of exposure. In a full-scale study, on a representative sample of the general population, it would probably not be essential to carry out personal air monitoring of cadmium. Personal monitoring of exposure to airborne lead might be useful, especially in areas with heavy traffic during seasons when people spend more time outdoors. For many of the women there were large day-to-day variations in the dietary intakes of lead and cadmium. Therefore the sampling periods should be as long as possible and preferably repeated. Identification of the food items responsible for the high peaks in the intake would make it possible to decrease the exposure considerably.

Acknowledgments

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Blood lead concentrations of Swedish preschool children in a community with high lead levels from mine waste in soil and dust

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BJERRE B, BERGLUND M, HARSBO K, HELLMAN B. Blood lead concentrations of Swedish preschool children in a community with high lead levels from mine waste in soil and dust. *Scand J Work Environ Health* 1993;19:154-61. The lead concentration in capillary blood was investigated in 49 preschool children (0.7-7.4 years of age) visiting a day-care center in a Swedish community with high lead contamination from mining and milling in soil and dust in populated areas [up to 1400 and 14 000 $\mu\text{g} \cdot \text{g}^{-1}$ (6.76 and 67.63 $\mu\text{mol} \cdot \text{g}^{-1}$) of dry weight, respectively]. The blood lead levels were examined twice (in April and in September) in 33 of the children. The lead levels were low on both sampling occasions [arithmetic mean 31 (SD 13, median 30, range 13-79) $\mu\text{g} \cdot \text{l}^{-1}$, ie, arithmetic mean 0.15, (SD 0.06, median 0.14, range 0.06-0.38) $\mu\text{mol} \cdot \text{l}^{-1}$]. Whereas children up to four years of age showed significantly increased levels from April to September, a significant decrease was seen in older children. The level of lead in soil at home, gender, smoking habits at home, and estimated level of hand-to-mouth activity did not appear as strong determinants of lead in blood. The results indicate that lead from mine waste in soil and dust fallout does not constitute a significant health hazard for preschool children in Falun.

Key terms: capillary blood, environmental lead, soil exposure.

Falun is a city in the middle of Sweden with about 50 000 inhabitants. For centuries the town has grown up around a thousand-year-old copper mine. The town is partly built on, and even by, mine deposits. There is some 10 000 t of lead in the waste dumps and residential fill materials scattered throughout the town area. Airborne dust from the mining and milling activities, various ore processing activities (eg, production of sulfuric acid), and extensive mine waste deposits have contributed to a significant metal contamination of the soil in the community. During some hundreds of years, until the 20th century, there were also extensive smelting activities in Falun.

Repeated measurements of lead in soil and dust fallout over the last few years have shown that the lead concentrations can be as high as 1400 $\mu\text{g} \cdot \text{g}^{-1}$ (6.76 $\mu\text{mol} \cdot \text{g}^{-1}$) of dry weight soil [geometric mean 362 (SD 2.3) $\mu\text{g} \cdot \text{g}^{-1}$, ie, geometric mean 1.75 (SD 0.01) $\mu\text{mol} \cdot \text{g}^{-1}$] and 14 000 $\mu\text{g} \cdot \text{g}^{-1}$ (67.63 $\mu\text{mol} \cdot \text{g}^{-1}$) of dust, in populated areas of the community. The

lead content in samples of soil taken at three different locations outside the city of Falun [geometric mean 119 (SD 1.6) $\mu\text{g} \cdot \text{g}^{-1}$, ie, geometric mean 0.57 (SD 0.01) $\mu\text{mol} \cdot \text{g}^{-1}$] was significantly lower ($P < 0.001$) than the mean lead content in the samples taken in the central areas of the community. Background values for lead in Swedish soils have been estimated to be 16 $\mu\text{g} \cdot \text{g}^{-1}$ (0.08 $\mu\text{mol} \cdot \text{g}^{-1}$) dry weight (1).

Young children have been identified as the particular group at risk in a general population continuously exposed to lead-contaminated soil and dust due to their normal hand-to-mouth activity and their greater susceptibility to and higher gastrointestinal absorption rate of lead (2-8). The principal sources of lead exposure differ between young children, older children, and adults. The younger children ingest more soil and dust than older children because of their more prominent hand-to-mouth activity. Blood lead levels have been shown to increase from about six months of age, peak at about one to four years of age, and thereafter decline with age (9-13).

Many organs may be adversely affected by lead. A major concern is its neurophysiological effects, typically manifested as deteriorated performances on various psychometric tests for cognitive functions or hyperactive behavior (14-19). Such effects have been observed at blood lead levels of 100-150 $\mu\text{g} \cdot \text{l}^{-1}$ (0.48-0.72 $\mu\text{mol} \cdot \text{l}^{-1}$) (7, 11, 20), and it has even been suggested that there is no distinct threshold for the adverse effect of lead on early cognitive development (20).

A theoretical risk assessment made specifically for the Falun area (Hellman; unpublished) was not able

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to exclude the possibility that blood lead levels were increased in certain infants living in heavily contaminated areas. Since this conclusion was in agreement with more general risk assessments made by others (21, 22), the present study was undertaken to determine the blood lead levels of a group of preschool children visiting a day-care center in Falun, where the lead content of soil and dust fallout is high.

Subjects and methods

Subjects

All children visiting a day-care center in Falun were offered the possibility to participate in a blood lead examination study through an invitation to their parents, who were also informed of the purposes of the study. The day-care center was the only one located in an area with notably high concentrations of lead in soil [about 1000 $\mu\text{g} \cdot \text{g}^{-1}$ (4.83 $\mu\text{mol} \cdot \text{g}^{-1}$) dry weight]. Blood samples were taken from 49 children (0.7–7.4 years of age) whose parents had accepted their participation. Only one child of the 50 children at the day-care center did not participate in the study.

Questionnaire

Information on present and previous home addresses and the birth date of the children was obtained from questionnaires given to the parents. Furthermore, information was collected about passive smoking (ie, number of smokers and number of cigarettes smoked per day in the home) and other possible sources of lead exposure at home [ie, the children's estimated intake of food from tin cans (0, 1–2, or >2 times per week) or the presence of a hobby involving a potential use of lead, such as soldering, welding, or pottering. The hand-to-mouth activity of each child was estimated by the parents on the basis of questions on how often their child put things into their mouth (never, sometimes, or often), used a pacifier or sucked fingers (never, sometimes, or often), and ate snow or soil (never, sometimes, or often). Information about how much time (estimated) the children spent outdoors per day was also obtained from the parents.

Blood sampling

The first blood sample was taken in April 1991 when the ground was still covered with snow (for about

four months). The second sample was taken in September of the same year (ie, at the end of the summer season when the children could be expected to have been exposed to outdoor soil and dust fallout for at least five months). The number and gender of the preschool children participating in the blood sampling in April and September 1991 is given in table 1.

The average age of the youngest children (up to four years of age) donating blood was 2.5 (range 1.2–3.0) years in April and 2.4 (range 0.7–3.5) years in September. The corresponding figures for the older children was 5.3 (range 3.8–7.2) years in April and 5.6 (range 4.2–7.4) years in September. The decrease in average age in the youngest group was explained by the increased number of young children attending the day-care center after the summer season. Thirty-three of the children donated blood on two occasions. Blood samples from the remaining 16 children were, for reasons already indicated, taken only on one of the two sampling occasions (3 children in April and 13 children in September).

Capillary blood samples (500 μl) were taken from the left hand of each child by a trained nurse. The hand and fingers were carefully cleaned with the use of a brush, soap, and water, followed by 1% nitric acid, to avoid contamination of blood from the skin. Sterile mini lancets (Clean Chemical, Sweden AB, Stockholm, Sweden) were used for the finger puncture. Blood was collected in acid-washed Microvette CB 1000 (Sarstedt, Stockholm, Sweden) with 5 μl of ethylenediaminetetraacetic acid (0.15 g EDTA \cdot ml⁻¹ water) added (1.5 mg EDTA \cdot ml⁻¹ blood). All of the material used for sampling was tested for metal content. The samples were kept deep-frozen until the analysis.

Sampling of soil and dust

The latest soil lead analyses, commissioned by the Local Health Committee, were performed in 1991 in Falun. Lead concentrations were measured in the top soil from 48 locations in populated areas of the community. These areas were located at different directions and distances from the mine waste deposits. A sample comprised the humus layer of the top soil (0–5 cm). In 1991, dust samples were taken once a month at seven different locations in the populated

Table 1. Characterization of the study group in relation to age, gender, and blood sampling occasion

Blood sampling occasion	Children ≤ 4 years of age			Children > 4 years of age			All children		
	Boys (N)	Girls (N)	Total (N)	Boys (N)	Girls (N)	Total (N)	Boys (N)	Girls (N)	Total (N)
April	7	4	11	17	8	25	24	12	36
September	12	7	19	19	8	27	31	15	46
Both April and September	6	4	10	16	7	23	22	11	33
Either April or September	13	7	20	20	9	29	33	16	49

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areas of the city. Each sample represented the total amount of dust collected during a month in a sampling container (inside diameter 0.2 m) placed 1.4 m above the ground.

Analysis of lead in blood

The blood samples were analyzed on two occasions at the Institute of Environmental Medicine. Each of the two analytical series included the analysis of quality control samples of bovine blood spiked with lead. Two subsamples of 0.1 ml of blood were deproteinized by the addition of 0.4 ml of 0.8 M nitric acid. The supernatant was analyzed using graphite furnace atomic absorption spectrophotometry (GFAAS) with background correction and peak area evaluation (Perkin-Elmer model 5000 Zeeman, HGA-500, autosampler AS-40, PE computer model 7500). The detection limit for the lead concentration of blood was $5 \mu\text{g} \cdot \text{l}^{-1}$ ($0.024 \mu\text{mol} \cdot \text{l}^{-1}$). The analytical performance was evaluated by a linear regression analysis of sets of quality control samples (23). The evaluation guaranteed, with the power of 90%, that the true regression line would not fall outside the maximum allowable deviation interval $y = x \pm (0.05x + 10)$ (figure 1). The error of the method was $3.82 \mu\text{g} \cdot \text{l}^{-1}$ ($0.018 \mu\text{mol} \cdot \text{l}^{-1}$) in the first analytical series and $3.35 \mu\text{g} \cdot \text{l}^{-1}$ ($0.016 \mu\text{mol} \cdot \text{l}^{-1}$) in the second series. Thus it can be assumed that the accuracy of the blood lead levels was satisfactory.

Analysis of lead in soil

The soil samples were analyzed at SGAB Analys, Luleå, Sweden, together with quality control samples prepared from a certified lake sediment reference

sample (BCR 280, Delta Instituut voor Hydrobiologisch onderzoek, The Netherlands). The soil was dried at 105°C and weighed before being dissolved in 50% nitric acid in a sealed Teflon® container, using a microwave oven. The solution was filtered and then diluted with distilled water before being analyzed using inductively coupled plasma source mass spectrometry (ICP-MS) (24).

Analysis of lead in dust

The dust samples were analyzed at the laboratory of the mining company Stora Teknik, Falun, together with quality control samples prepared from a standard solution of lead in water (Titrisol, Merck, Darmstadt, Germany). The dust collector was washed out, and the entire content was dried before being dissolved in 20 ml of 7 M nitric acid. The lead content in aliquots of the dissolved samples was determined by atomic absorption spectrometry (AAS), using a Perkin-Elmer model 4000.

Statistical evaluation of the data

Statistical significance was judged according to the unpaired Mann-Whitney two-sample test, Mann-Whitney U statistics being employed for individual data. When blood lead levels before and after the summer season were compared for the 33 individuals donating blood in both April and September, the data were analyzed with the Wilcoxon signed rank test. Least squares linear regression analysis was used as an additional test when the impact of age and the soil lead level at home on the blood lead concentration was analyzed. Student's t-test of differences between the mean values was used when soil lead lev-

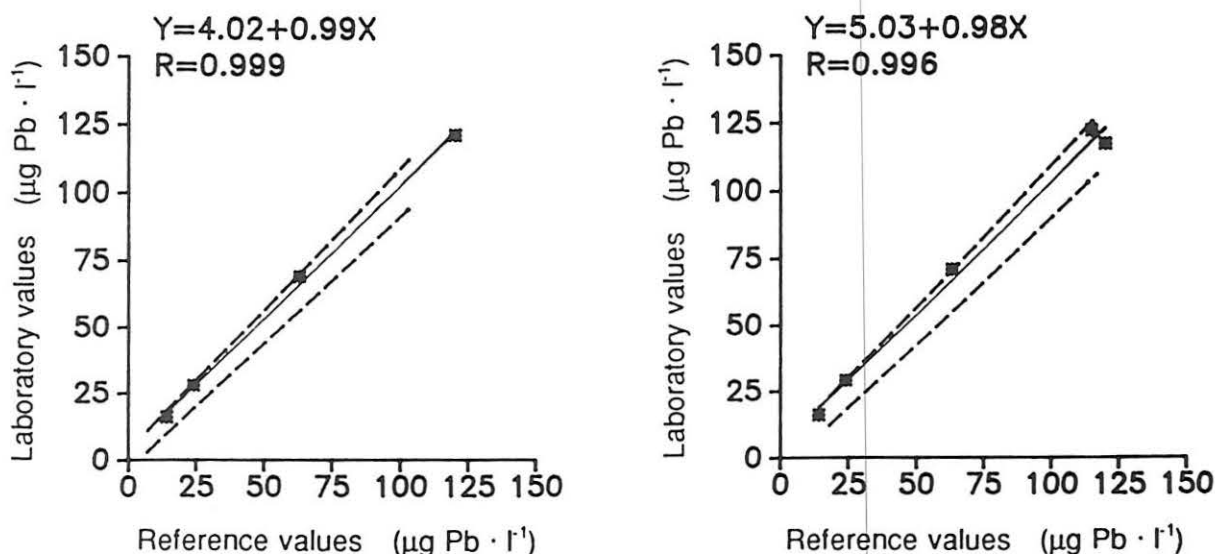


Figure 1. Analytical quality control for lead (Pb) in blood. Quality control samples analyzed together with the collected blood samples in May (left) and in October (right). The analytical performance was evaluated by linear regression of the reference values versus the laboratory results. The maximum allowable deviation interval (broken lines) is given by $y = x \pm (0.05x + 10)$. ($1 \mu\text{g Pb} \cdot \text{l}^{-1} = 0.0048 \mu\text{mol} \cdot \text{l}^{-1}$)

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Is	Total (N)
2	36
3	46
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els (geometric means) at different locations were compared. Two-tailed statistics were used in all of the calculations. The level of significance was set at 5%.

Results

Soil analyses (7 in 1981, 22 in 1986, and 48 in 1991) made it possible to divide the city into four zones with regard to the soil lead concentration: ≤ 200 , 201–400, 401–600, and 601–1400 $\mu\text{g} \cdot \text{g}^{-1}$ (≤ 0.97 , 0.97–1.93, 1.94–2.90, and 2.90–6.76 $\mu\text{mol} \cdot \text{g}^{-1}$). Most of the children (71%) lived in areas with soil lead concentrations of 601–1400 $\mu\text{g} \cdot \text{g}^{-1}$ (2.90–6.76 $\mu\text{mol} \cdot \text{g}^{-1}$). Only one child lived in an area with a soil lead concentration below 200 $\mu\text{g} \cdot \text{g}^{-1}$ (0.97 $\mu\text{mol} \cdot \text{g}^{-1}$). The children had not changed home addresses during the year preceding the study. The day-care center was located in the zone with a soil lead concentration of 601–1400 $\mu\text{g} \cdot \text{g}^{-1}$ (2.90–6.76 $\mu\text{mol} \cdot \text{g}^{-1}$). The lead content in the dust fallout measured close to the day-care center varied between 350 and 3500 $\mu\text{g} \cdot \text{g}^{-1}$ over the year.

The average (arithmetic mean) blood lead level for all of the children included in the study was 31 (SD 13, range 13–79, median 30) $\mu\text{g} \cdot \text{l}^{-1}$ [0.15 (SD 0.06, range 0.06–0.38, median 0.14) $\mu\text{mol} \cdot \text{l}^{-1}$] in April (36 children), and 32 (SD 13, range 13–69, median 30) $\mu\text{g} \cdot \text{l}^{-1}$ [0.15 (SD 0.06, range 0.06–0.33, median 0.14) $\mu\text{mol} \cdot \text{l}^{-1}$] in September (46 children). The correlation between the blood lead levels and age,

gender, soil lead level, and smoking habits in the home for the children donating blood in September 1991 is shown in table 2. To study the effect of seasonal variation, we made a pairwise comparison of the blood lead levels of the 33 individuals donating blood in both April and September (table 2). Whereas a paired nonparametric test was used to analyze whether the median blood lead levels differed significantly from April to September, an unpaired nonparametric test was used to examine whether the median blood lead levels differed between the groups for the other parameters. It was not possible to carry out any meaningful multiple variate analysis because of the small number of children included in the study.

When the children participating in the blood sampling in September were divided into two age groups (four years of age or younger in September and older than four years of age in September), the younger children were found to have significantly ($P=0.04$) higher blood lead levels than the older children (table 2). This difference was confirmed when the data were analyzed with the use of least squares linear regression (figure 2). In April the situation was just the opposite, namely, the youngest children were found to have significantly lower ($P=0.03$) blood lead levels than the older children.

Whereas the blood lead concentrations increased significantly (32%) ($P=0.008$) over the summer season among the children four years of age or younger from 25 (SD 8) $\mu\text{g} \cdot \text{l}^{-1}$ [0.12 (SD 0.04) $\mu\text{mol} \cdot \text{l}^{-1}$]

Table 2. Effects of various study parameters on the blood lead levels of preschool children living in a community with high concentrations of lead from mine waste in soil and dust.

Parameter	Blood lead level ($\mu\text{g} \cdot \text{l}^{-1}$) ^a				
	Mean	SD	Range	Median	P-value ^b
Age ^c					
A. ≤ 4 years (N = 20)	37	15	14–69	35	0.04 ^d
B. > 4 years (N = 26)	28	10	13–60	26	
Gender ^c					
A. Boys (N = 31)	31	14	13–69	26	0.19 ^d
B. Girls (N = 15)	34	12	16–61	36	
Soil lead concentration at home ^c					
A. 0–600 $\mu\text{g} \cdot \text{g}^{-1}$ (N = 14)	27	8	13–40	28	0.17 ^d
B. 601–1400 $\mu\text{g} \cdot \text{g}^{-1}$ (N = 32)	34	14	16–69	32	
Smoking habits in the home ^c					
A. No smokers (N = 35)	31	14	13–69	27	0.09 ^d
B. Smokers (N = 11)	34	7	21–46	35	
Seasonal variation					
A. April, all children (N = 33)	32	13	13–79	29	0.51 ^e
B. September, all children (N = 33)	30	12	13–68	27	
A. April, ≤ 4 years of age (N = 10)	25	8	13–40	26	0.008 ^e
B. September, ≤ 4 years of age (N = 10)	33	14	14–68	34	
A. April, > 4 years (N = 23)	34	14	16–79	32	0.005 ^e
B. September, > 4 years (N = 23)	28	11	13–60	26	

^a 1 $\mu\text{g} \cdot \text{l}^{-1}$ = 0.0048 $\mu\text{mol} \cdot \text{l}^{-1}$

^b A–B.

^c September study.

^d Mann-Whitney two-sample test (Mann-Whitney U-statistics).

^e Wilcoxon signed rank test of data obtained from individuals donating capillary blood in both April and September.

Blood lead ($\mu\text{g} \cdot \text{l}^{-1}$)

Blood lead ($\mu\text{g} \cdot \text{l}^{-1}$)

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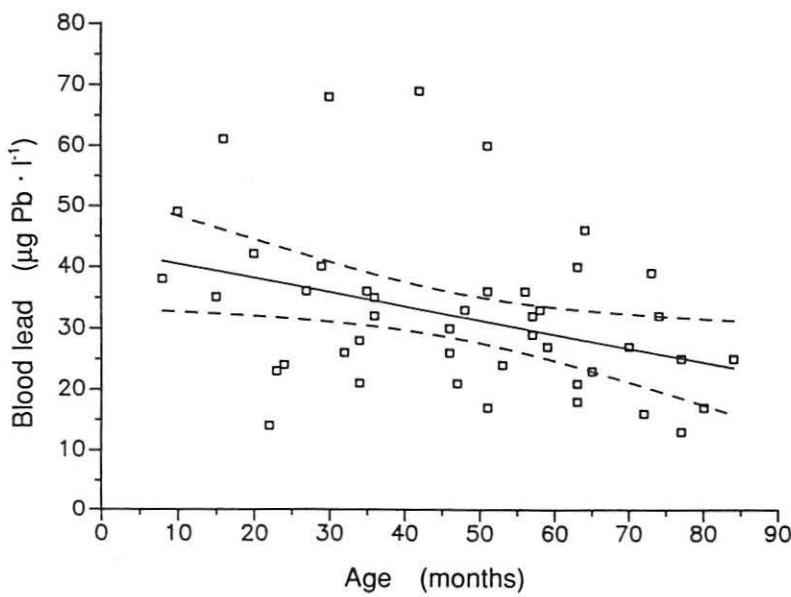


Figure 2. Relationship between blood lead levels and age (September 1991). The linear regression values are as follows: correlation coefficient $r = -0.353$ ($r^2: 0.124$), slope = -0.23 (95% confidence interval: -0.41 to -0.04), and two-tailed P-value = 0.016 (ie, the slope is significantly different from zero). ($1 \mu\text{g} \cdot \text{l}^{-1} = 0.0048 \mu\text{mol} \cdot \text{l}^{-1}$)

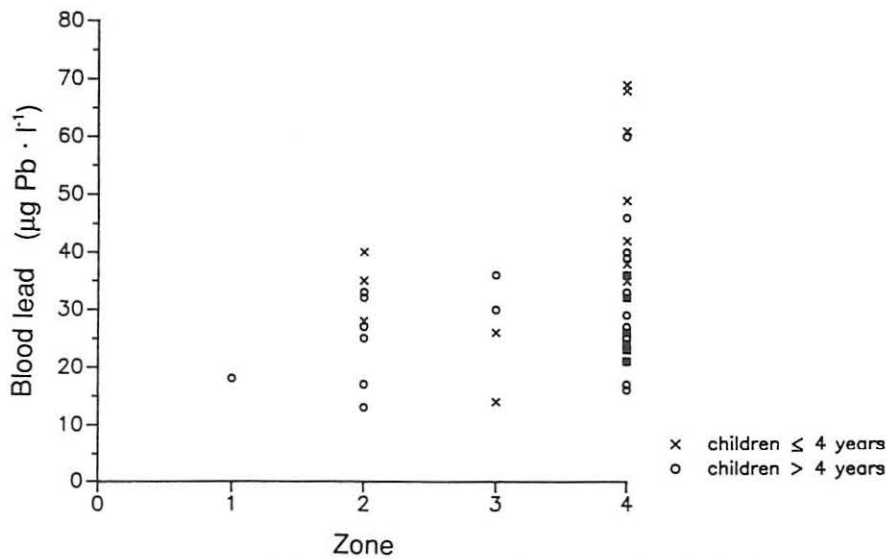


Figure 3. Relationship between blood lead and soil lead (September 1991). The inhabited areas of Falun were divided into four zones (zone 1: $\leq 200 \mu\text{g} \cdot \text{g}^{-1}$ soil, zone 2: $201-400 \mu\text{g} \cdot \text{g}^{-1}$, zone 3: $401-600 \mu\text{g} \cdot \text{g}^{-1}$, and zone 4: $601-1400 \mu\text{g} \cdot \text{g}^{-1}$). The linear regression values are as follows: correlation coefficient $r = 0.2640$ ($r^2: 0.0697$), slope = 3.92 (95% confidence interval: -0.31 to 8.16), and two-tailed P-value = 0.0762 (ie, the slope was not significantly different from zero). ($1 \mu\text{g} \cdot \text{l}^{-1} = 0.0048 \mu\text{mol} \cdot \text{l}^{-1}$)

to 33 (SD 14) $\mu\text{g} \cdot \text{l}^{-1}$ [0.16 (SD 0.07) $\mu\text{mol} \cdot \text{l}^{-1}$], there was a significant decrease (18%) ($P=0.005$) among the older ones, from 34 (SD 14) $\mu\text{g} \cdot \text{l}^{-1}$ [0.16 (SD 0.07) $\mu\text{mol} \cdot \text{l}^{-1}$] to 28 (SD 11) $\mu\text{g} \cdot \text{l}^{-1}$ [0.14 (SD 0.05) $\mu\text{mol} \cdot \text{l}^{-1}$]. Among the 33 children donating blood in both April and September, 18 (average age 5.2 years) had blood lead levels that had decreased from April to September, and 13 children (average age 3.5 years) had increased levels. The highest blood lead level ($79 \mu\text{g} \cdot \text{l}^{-1}$, ie, $0.38 \mu\text{mol} \cdot \text{l}^{-1}$) was observed in April in a boy (4.2 years of age) living in an area with a soil lead level of $>600 \mu\text{g} \cdot \text{g}^{-1}$ ($>2.90 \mu\text{mol} \cdot \text{g}^{-1}$). In September, his blood lead level was $60 \mu\text{g} \cdot \text{l}^{-1}$ ($0.29 \mu\text{mol} \cdot \text{l}^{-1}$). The next two highest blood lead levels (69 and $68 \mu\text{g} \cdot \text{l}^{-1}$, ie, $0.33 \mu\text{mol} \cdot \text{l}^{-1}$)

l^{-1}) were observed in two boys (3.5 and 2.9 years of age, respectively) in September. They were both living in areas with a soil lead level of $>600 \mu\text{g} \cdot \text{g}^{-1}$ ($>2.90 \mu\text{mol} \cdot \text{g}^{-1}$). None of these three boys had smoking parents.

Eleven of the children donating blood in September lived in homes with smoking family members. (Only two of them lived in homes with family members smoking more than 20 cigarettes per day.) Children older than four years of age and exposed to passive smoking at home ($N=6$) had significantly higher blood lead levels ($P=0.03$) than those living in homes without smoking family members ($N=22$). However, since there was no effect of passive smoking at home on the blood lead levels, neither among

the older children donating blood in April nor among the younger children, this parameter was judged to be of minor importance in the present study.

As shown in table 2 and figure 3, there was a tendency towards increased blood lead levels in the children living in areas with a soil lead level of $>600 \mu\text{g} \cdot \text{g}^{-1}$ ($>2.90 \mu\text{mol} \cdot \text{g}^{-1}$). However, neither this parameter nor the gender of the children (table 2), the parents' estimations of the hand-to-mouth activity, the consumption of canned food of the children (not shown), nor the presence of hobbies at home possibly involving the use of lead (not shown) were found to have a statistically significant correlation with the blood lead levels. However, it should be pointed out that the groups were relatively small, and it was not possible to standardize for age and soil lead concentration at home.

Discussion

In the present study, blood lead levels were measured in preschool children living in a Swedish community with high levels of lead from mine waste in soil and dust fallout. Despite the fact that the children were selected to represent a group with a potential exposure to soil and dust with high concentrations of lead, the blood lead levels were found to be relatively low. The average blood lead level was $31 \mu\text{g} \cdot \text{l}^{-1}$ ($0.15 \mu\text{mol} \cdot \text{l}^{-1}$) in April and $32 \mu\text{g} \cdot \text{l}^{-1}$ ($0.15 \mu\text{mol} \cdot \text{l}^{-1}$) in September.

Previous Swedish studies of blood lead levels among older schoolchildren (14 to 15 years of age, some of whom were from Falun) showed a mean blood lead level of $26 \mu\text{g} \cdot \text{l}^{-1}$ ($0.12 \mu\text{mol} \cdot \text{l}^{-1}$), with a median value of $21 \mu\text{g} \cdot \text{l}^{-1}$ ($0.10 \mu\text{mol} \cdot \text{l}^{-1}$) and a range between <10 and $273 \mu\text{g} \cdot \text{l}^{-1}$ (<0.05 and $1.32 \mu\text{mol} \cdot \text{l}^{-1}$) (25). Schoolchildren (8 to 13 years of age) in a glassworks area with lead-emitting industries and a reference area, in the south of Sweden, had a mean blood lead level of $35 \mu\text{g} \cdot \text{l}^{-1}$ ($0.17 \mu\text{mol} \cdot \text{l}^{-1}$), with a range between 10 and $89 \mu\text{g} \cdot \text{l}^{-1}$ (0.05 and $0.43 \mu\text{mol} \cdot \text{l}^{-1}$) (26). There was no difference in the blood lead levels between the areas. Blood lead levels have been monitored among schoolchildren (mean age 11 years) in the south of Sweden, in both urban and rural areas, since 1978. In 1988, the mean blood lead level was $33 \mu\text{g} \cdot \text{l}^{-1}$ ($0.16 \mu\text{mol} \cdot \text{l}^{-1}$), with a range between 15 and $71 \mu\text{g} \cdot \text{l}^{-1}$ (0.07 and $0.34 \mu\text{mol} \cdot \text{l}^{-1}$) (27). The indicated blood lead levels among Swedish schoolchildren are similar to those found in the general Swedish adult population (28, 29).

In the aforementioned studies, blood was collected from the cubital vein. The risk for contamination of the blood is higher with the finger puncture technique than with venipuncture. However, good agreement between the two methods has been achieved when measures have been taken to eliminate the risk for contamination (30). We tested our sampling tech-

nique by collecting blood from the cubital vein and from finger puncture from adults. It was shown that blood could be collected with the finger puncture technique without contaminating the blood with lead (Berglund et al, unpublished results).

A reasonable explanation for the observed increase in blood lead levels from April to September among the youngest children (up to four years of age) could be that the daily intake of soil and dust during the summer season is higher among younger children because of more prominent hand-to-mouth activity. To confirm and further elucidate our findings, additional investigations are needed. However, seasonal patterns in blood lead levels, with a minimum in the winter and a maximum in the summer, have been observed in various blood screening programs (31, 32), and it has also been shown that children under three years of age are at the greatest risk of showing an increase in blood lead level during the summer season (31).

One explanation for the observed low blood lead levels in Falun is that the lead compounds present in soil and dust fallout have a low bioavailability. It is known that young children can absorb up to 40–50% of ingested lead (33, 34). Such a high absorption rate may not be true for older children or for lead in the form of lead sulfide, mainly present in the soil and dust contaminated by mine waste from Falun (Qvarfort, personal communication).

Another possible explanation for the relatively low blood lead levels in the preschool children from Falun could be that these children were not exposed to soil and dust to the extent expected or that the lead levels measured in the soil and dust were not representative of what was generally available to the children. Blood lead level is a measure of recent total lead exposure. However, due to the design of the study, and the restricted number of children, it has not been possible to assess the relative importance of lead from lead-contaminated soil and dust. It is, for example, not known how much lead each child in the study ingested via food and water.

Several attempts have been made to estimate the amount of soil and dust ingested by young children (6, 35–38) and to predict the blood lead levels of children from the concentration of lead in the soil and dust in their surroundings (3, 39–41). When Steele et al (42) investigated the relationships between soil and blood lead concentrations in residents living in communities with lead-contaminated soil, they found that the impact of lead derived from mine waste on the blood lead levels was less than that for lead in soil derived from smelter, vehicle, or paint sources. It was suggested that the low bioavailability of lead derived from mine waste (ie, lead sulfide) could be explained by the relatively large particle sizes typically observed in mine wastes, and also by the low solubility of lead sulfide.

The idea that lead derived from mines appears to have a low bioavailability is supported also by health

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survey data from other "mining" communities with elevated levels of lead in the soil (43). Studying the bioavailability of inorganic lead in rats after oral administration, Freeman et al (44) observed that only a small fraction of lead was absorbed from soil contaminated by mine waste in comparison with lead acetate. In contrast to the observations made from rats, LaVelle et al (45) reported a relatively high bioavailability of lead derived from mine waste in soil given orally to young pigs.

In children up to four years of age, blood lead levels increased during the summer season. This finding indicated that mine-waste lead in soil contributed to the total lead exposure. However, the blood lead levels measured in the preschool children from Falun did not indicate a significant risk of adverse health effects. Our study suggests a low bioavailability of lead deposited in soil and dust during mining, milling, and ancient smelting activities, as well as during modern processing activities such as sulfuric acid production. At least in Falun, it appears as if these sources of lead do not constitute the same environmental health hazard for children as other lead sources do, for example, emissions from modern smelters, vehicle exhaust, and lead-based paints. Thus it seems clear that the bioavailability of various types of lead contamination should be considered when the risk of health effects due to contaminated soil are assessed, and before extensive clean-up actions are initiated.

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Final Ozone NAAQS	7-18-97	242616	
Final Particulate Matter NAAQS	7-18-97	1373408	
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costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities. Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of E.O. 13084 do not apply to this rule.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This final rule will not have a significant impact on a substantial number of small entities because SIP approvals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial

prepare a budgetary impact statement to accompany any proposed or final rule that includes a federal mandate that may result in estimated annual costs to state, local, or tribal governments in the aggregate, or to the private sector, of \$100 million or more. Under Section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that this approval action does not include a federal mandate that may result in estimated annual costs of \$100 million or more to either state, local, or tribal governments in the aggregate, or to the private sector. This federal action approves preexisting requirements under state or local law, and imposes no new requirements. Accordingly, no additional costs to state, local, or tribal governments, or to the private sector, result from this action.

G. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the Federal Register. This rule is not a "major" rule as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 58

Environmental protection, Air pollution control, Ozone, Oregon, Reporting and recordkeeping requirements, Washington.

Dated: January 7, 1999.

Chuck Clarke,
Regional Administrator, Region 10.

Part 58, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 58—[AMENDED]

1. The authority citation for Part 58 continues to read as follows:

Authority: 42 U.S.C. 7401 et seq.

2. Part 58, Appendix D, section 2.5: the table is amended by revising the entry for Oregon and Washington to read as follows:

Appendix D—Network Design for State and Local Air Monitoring Stations (SLAMS) and National Air Monitoring Stations (NAMS) and Photochemical Assessment Monitoring Stations (PAMS)

* * * * *

2.5 Ozone (O3) Design Criteria for SLAMS

* * * * *

OZONE MONITORING SEASON BY STATE

State	Begin Month	End Month
Oregon	May	September
Washington	May	September

have decreased 97 percent between 1978 and 1997 with the elimination of lead in gasoline used by on-road mobile sources. Because of this historic decrease, EPA is reducing its requirements for measuring lead air pollutant concentrations near major highways, while retaining its focus on point sources and their impact on neighboring populations. The EPA published a direct final rule for ambient air quality surveillance for lead on November 5, 1997 (62 FR 59813). Due to adverse comments received, the rule was withdrawn on December 23, 1997 (62 FR 67009). Based on comments that were received, today's action revises 40 CFR part 58 lead air monitoring regulations to allow many lead monitoring stations to be discontinued while maintaining a core lead monitoring network in urban areas to track continued compliance with the lead National Ambient Air Quality Standards (NAAQS). This action does not diminish existing requirements for lead ambient air monitoring around lead point sources. Approximately 70 of the National Air Monitoring Stations (NAMS) and a number of the State and Local Air Monitoring Stations (SLAMS) could be discontinued with this action, thus making more resources available to those State and local agencies to deploy lead air quality monitors around heretofore unmonitored lead point sources. Affected industries include primary and secondary lead smelting, lead battery recycling, and primary copper smelting.

DATE: The effective date of this rule is February 19, 1998.

ADDRESSES: All comments relative to this rule have been placed in Docket No. A-91-22, located in the Air Docket (LE-131), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460. The docket may be inspected between 8 a.m. and 5:30 p.m., Monday through Friday, excluding legal holidays. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: For general information, contact Brenda Millar, Emissions, Monitoring, and Analysis Division (MD-14), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Telephone: (919) 541-4036, e-mail: millar.brenda@epa.gov. For technical information, contact Michael Jones, Emissions Monitoring, and Analysis Division (MD-14), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina

27711, Telephone: (919) 541-0528, e-mail: jones.mike@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Authority

Sections 110, 301(a), and 319 of the Clean Air Act as amended 42 U.S.C. 7410, 7801(a), 7819.

II. Background

The current ambient air monitoring regulations that pertain to lead air sampling were written in the 1970's when lead emissions from on-road mobile sources (e.g., automobiles, trucks) were the predominant lead air emission source affecting our communities. As such, the current lead monitoring requirements focus primarily upon the idea of determining the air quality impacts from major roadways and urban traffic arterial highways. Since the 1970's, lead has been removed from gasoline sources for on-road vehicles (on-road vehicles now account for less than 1 percent of total lead emissions), and a 97 percent decrease in lead air pollution levels measured in our neighborhoods and near roadways has occurred nationwide. Because of this historic decrease, EPA is reducing its requirements for measuring lead air pollutant concentrations near major highways, while retaining its focus on point sources and their impacts on neighboring populations.

Several commenters observed that the rule's assessment of on-road vehicle emissions is contrary to the Agency's own figures. Specifically, the proposed rule stated that on-road vehicle emissions account for less than 1 percent of total lead emissions, while the Agency's 1995 National Air Quality and Emissions Trends Report (EPA 454/R-96-005) indicated that nearly 28 percent of total air lead emissions were attributable to on-road vehicles.

Based on the emissions reported in "Locating and Estimating Air Emissions from Sources of Lead and Lead Compounds" (Eastern Research Group, Draft Report, July 1996), on-road vehicle emissions had been over estimated. The EPA investigated this inconsistency and found due cause to revise on-road vehicle emissions estimates. These revisions are reflected in subsequent Agency reports (e.g., EPA 454/R-97-011, "National Air Pollutant Emission Trends, 1900-1996", EPA 454/R-97013, "National Air Quality and Trends Report, 1996," and EPA 454/R-98-016, "National Air Quality and Trends Report, 1997") wherein on-road vehicle emissions are listed as contributing approximately 0.5 percent of the total lead estimate.

Several commenters questioned the rule's asserted need for additional monitors around stationary point sources, particularly the basis for increased scrutiny of stationary sources emitting five or more tons per year, as well as, in select cases, those sources emitting less than 5 tons per year. Further, the potential for increased information collection burden, and means of determining which "smaller stationary sources" would be considered "problematic" were also questioned.

The primary objective of this rule is to reduce the requirement for lead air pollutant concentration measurements near major highways, while maintaining a focus on lead point sources and their impact on neighboring populations. The EPA has determined that, in the interest of furthering attainment of the National Ambient Air Quality Standard (NAAQS) for lead, it is prudent for State and local agencies to deploy these additional lead monitoring resources in the vicinity of any previously unmonitored point source which they feel may have the potential to cause lead air quality violations. A point source is defined in 40 CFR 51.100(k)(2) as "For lead or lead compounds measured as lead, any stationary source that actually emits a total of 4.5 metric tons (5 tons) per year or more." Though the verbiage " * * * although smaller stationary sources may also be problematic depending upon the facility's size and proximity to neighborhoods" was removed from this rule, State and local agencies are not precluded from further evaluating any lead source which they feel may have the potential to violate lead air quality standards. Suggested guidelines for such source evaluations are described in "Screening Procedures for Estimating the Air Quality Impact of Stationary Sources, Revised" (EPA 454/R-92-019). Finally, ambient lead monitoring occurs at existing major primary and secondary lead smelters, lead acid battery plants, and primary copper smelters. As essentially all quantifiable lead point sources are included in these categories, and considering the substantial decrease in roadside monitoring which will result from this rule, EPA believes this rule will entail little or no increased information collection burden.

A State requested that EPA amend the referenced rule to delete the requirement for one NAMS population-oriented site in the vicinity of a specific facility within their jurisdiction.

The monitoring site north of the facility in question has reported lead NAAQS violations in 1 or 2 quarters during each of the past 3 years. Given that this monitor is sited at the middle

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scale, it is not unreasonable to require a NAMS site on the neighborhood scale. Data from such a site are useful in representing typical air quality values for nearby residential areas, and suitable for population exposure and trends analysis.

The current lead air monitoring regulations require that each urbanized area with a population of 500,000 or more operate at least two lead NAMS, one of which must be a roadway-

oriented site and the second must be a neighborhood site with nearby traffic arteries or other major roadways. There are approximately 58 NAMS in operation and reporting data for 1998. This action would change this NAMS requirement to include one NAMS site in one of the two largest Metropolitan Statistical Areas (MSA/CMSA) within each of the ten EPA Regions, and one NAMS population-oriented site in each populated area (either a MSA/CMSA,

town, or county) where lead violations have been measured over the most recent 8 calendar quarters. This latter requirement is designed to provide information to citizens living in areas that have one or more lead point sources that are causing recent air quality violations. At present, the MSA/CMSAs, cities, or counties that have one or more quarterly Pb NAAQS violations that may be subject to this requirement are listed in Table 1.

TABLE 1.—CMSA/MSA'S OR COUNTIES WITH ONE OR MORE LEAD NAAQS VIOLATIONS IN 1996-1997

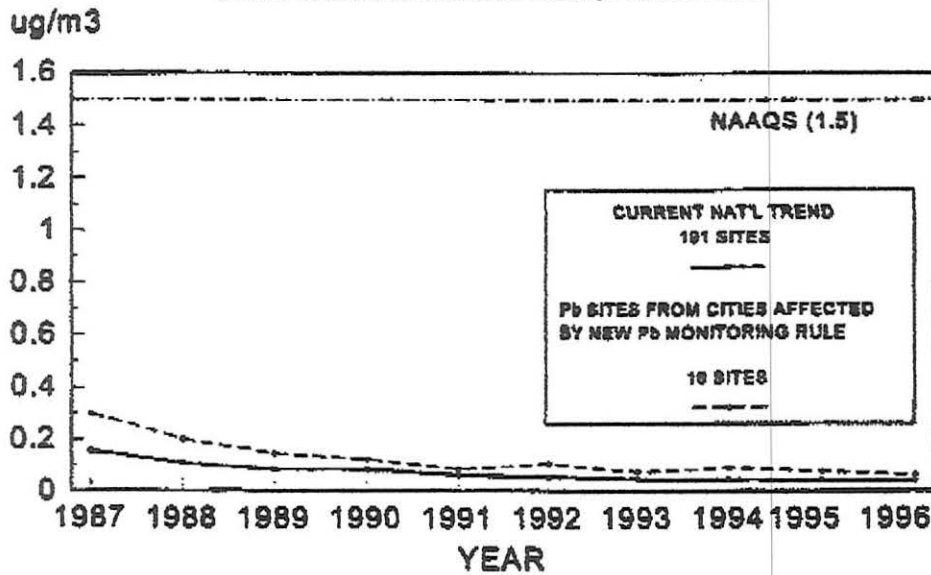
CMSA/MSA or County	Contributing Lead Source(s)
Philadelphia-Wilmington-Atlantic City CMSA	Franklin Smelter in Philadelphia County, PA.
Tampa-St. Petersburg-Clearwater MSA	Gulf Coast Lead in Hillsborough County, FL.
Memphis MSA	Refined Metals in Shelby County, TN.
Nashville MSA	General Smelting in Williamson County, TN.
St. Louis MSA	Chemtco in Madison County, IL, and Doe Run in Jefferson County, MO.
Cleveland-Akron CMSA	Master Metals in Cuyahoga County, OH.
Iron County, MO	ASARCO in/near Hogan, MO.
Omaha MSA	ASARCO in Douglas County, NE.
Lewis and Clark County, MT	ASARCO in/near East Helena, MT.

Data from these NAMS will be used to assess national trends in lead ambient

air pollution. Figure 1 demonstrates the effect that these monitoring reductions

will have on our national lead air pollutant trends.

FIGURE 1. LEAD TRENDS: CURRENT U.S. VS SELECTED CITIES COMPOSITE MAX QUARTERLY AVERAGE



For other monitoring within the SLAMS network, EPA is allowing State and local agencies to further focus their efforts toward establishing air monitoring networks around lead point sources which are causing or have a potential to cause exceedances of the

quarterly lead NAAQS. Many of these sources have been identified through EPA's ongoing Lead NAAQS Attainment Strategy, and monitoring has already been established. All point sources (stationary sources emitting five or more tons per year) are considered to be

candidates for additional lead monitoring. The EPA recommends a minimum of two sites per source, one located for stack emission impacts and the other for fugitive emission impacts. Variations of this two-site network are expected as source type, topography,

locations of neighboring populations, and other factors play a role in how to most appropriately design such a network. EPA guidance for lead monitoring around point sources has been developed and is available through a variety of sources including the National Technical Information Service (800-553-6847), and electronic forms accessible through EPA's Office of Air Quality Planning & Standards Technology Transfer Network, Ambient Monitoring Technology Information Center (AMTIC) bulletin board system at <http://ttrwww.rtpnc.epa.gov>.

One commenter questioned the rule's consistency with statutory mandates under section 319 of the Clean Air Act (CAA), in particular by citing the requirement for "uniform air quality criteria * * * throughout the United States." 42 U.S.C. 7619.

In section 319 of the CAA, the term "criteria" refers to a specific set of pollutants and the associated levels and forms of their respective standards. The term "uniform" refers to both criteria and measurement methodology, relative to a specific air quality index.

Uniformity in ambient monitoring is achieved by monitor design specifications (40 CFR part 53) and quality assurance/quality control procedures. Monitors which meet such design specifications are designated as either Federal Reference Method (FRM) or Federal Equivalent Method (FEM), as appropriate. Further, upon reading the entire text of the CAA, section 319, from which the commenter's excerpt was taken, it becomes clear that the new rule is, in fact, consistent with the referenced statutory mandates.

Several commenters noted that this rule is being issued in response to numerous State and local agency requests, yet the docket contains no documentation of such requests.

As many roadside monitored ambient lead values have steadily declined to at or near minimally detectable levels, the need for continued roadside ambient lead monitoring has been increasingly and repeatedly questioned by State representatives at the biannual Standing Air Monitoring Work Group meetings, as well as several instances of written queries and requests. The reason the Agency did not include any such existing documentation in the docket is that the basis for this rule revision is not requests from State and local agencies, but rather EPA's success in essentially eliminating on-road mobile source lead emissions. Given the fact that on-road mobile sources' contribution to the total lead emissions estimate is negligible, as evidenced by minimally detectable ambient levels at all locations other than

sites in proximity to lead point sources, it is EPA's inherent responsibility to ensure our nation's ambient air pollution monitoring resources are redirected toward environmental issues of concern.

Several commenters expressed concern over potential data misuse in commencement of unjustified enforcement proceedings or citizen suits. The reason for concern was cited as the combined impact of the proposed revisions to 40 CFR part 58 and EPA's Credible Evidence revisions to 40 CFR parts 51, 52, 60, and 61.

The referenced Credible Evidence revisions and related amendments to 40 CFR part 64, Compliance Assurance Monitoring, pertain exclusively to emissions monitoring data, not ambient air quality data. The proposed revisions to 40 CFR part 58, Ambient Air Quality Surveillance, do not allow for use of non-reference data in any compliance or enforcement actions. There is, therefore, no plausible potential for data misuse in commencement of unjustified enforcement proceedings or citizen suits.

In addition to the changes to the lead monitoring requirements, EPA is making several minor changes to update and correct regulatory provisions to current practices. Specifically this affects §§ 58.31, 58.34, 58.41, Appendix B, Appendix D Sections 3.2 and 3.3, and Appendix G, Sections 1 and 2b.

III. Administrative Requirements

A. Executive Order 12866

Under Executive Order 12866 (58 F.R. 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to Office of Management and Budget (OMB) review and to the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

It has been determined that this action is not a "significant regulatory action" under the terms of the Executive Order 12866 and is therefore not subject to formal OMB review.

B. Paperwork Reduction Act

Today's action does not impose any new information collection burden. This action revises the part 58 air monitoring regulations for lead to allow many monitoring sites to be discontinued. The Office of Management and Budget (OMB) has previously approved the information collection requirements in the part 58 regulation under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2060-0084 (EPA ICR No. 0940.13 and revised by 0940.14).

C. Executive Order 12875 Enhancing the Intergovernmental Partnership

Under Executive Order 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments, or EPA consults with those governments. If EPA consults with those governments, Executive Order 12875 requires EPA to provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and tribal governments "to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates."

Today's rule implements requirements specifically set forth by the Congress in 42 U.S.C. 7410 without the exercise of any discretion by EPA. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

D. Executive Order 13045

Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), applies to any rule that the EPA determines (1) is "economically significant," as defined under Executive Order 12866, and (2) the environmental

4. Section 58.41(b) is revised to read as follows:

§ 58.41 PAMS network description.

(b) The AIRS site identification number for existing stations.

5. Appendix D is amended by revising the first sentence of the undesignated paragraph following paragraph (6) of section 1, revising section 2.7, revising the fifth paragraph of section 3, revising the last sentence of the first paragraph of section 3.2, revising the last sentence of the first paragraph of section 3.3, revising section 3.6, and revising references 8, 7, 10 of section 6 and adding reference 19 to section 6 to read as follows:

Appendix D—Network Design for State and Local Air Monitoring Stations (SLAMS), National Air Monitoring Stations (NAMS), and Photochemical Assessment Monitoring Stations (PAMS)

1. SLAMS Monitoring Objectives and Spatial Scales

It should be noted that this appendix contains no criteria for determining the total number of stations in SLAMS networks, except in areas where Pb concentrations currently exceed or have exceeded the Pb NAAQS during any one quarter of the most recent eight quarters.

2.7 Lead (Pb) Design Criteria for SLAMS. Presently, less than 1 percent of the Nation's Pb air pollution emissions originate from on-road mobile source exhaust. The majority of Pb emissions come from point sources, such as metals processing facilities, waste disposal and recycling, and fuel combustion (reference 19 of this appendix). The SLAMS networks are used to assess the air quality impacts of Pb point sources, and to determine the broad population exposure from any Pb source. The most important spatial scales to effectively characterize the emissions from point sources are the micro, middle, and neighborhood scales. For purposes of establishing monitoring stations to represent large homogeneous areas other than the above scales of representativeness, urban or regional scale stations may also be needed.

Microscale—This scale would typify areas in close proximity to lead point sources. Emissions from point sources such as primary and secondary lead smelters, and primary copper smelters may under fumigation conditions likewise result in high ground level concentrations at the microscale. In the latter case, the microscale would represent an area impacted by the plume with dimensions extending up to approximately 100 meters. Data collected at microscale stations provide information for evaluating and developing "hot-spot" control measures.

Middle Scale—This scale generally represents Pb air quality levels in areas up to several city blocks in size with dimensions on the order of approximately 100 meters to 500 meters. The middle scale may for example, include schools and playgrounds in center city areas which are close to major Pb point sources. Pb monitors in such areas are desirable because of the higher sensitivity of children to exposures of elevated Pb concentrations (reference 7 of this appendix). Emissions from point sources frequently impact on areas at which single sites may be located to measure concentrations representing middle spatial scales.

Neighborhood Scale—The neighborhood scale would characterize air quality conditions throughout some relatively uniform land use areas with dimensions in the 0.5 to 4.0 kilometer range. Stations of this scale would provide monitoring data in areas representing conditions where children live and play. Monitoring in such areas is important since this segment of the population is more susceptible to the effects of Pb. Where a neighborhood site is located away from immediate Pb sources, the site may be very useful in representing typical air quality values for a larger residential area, and therefore suitable for population exposure and trends analyses.

Urban Scale—Such stations would be used to present ambient Pb concentrations over an entire metropolitan area with dimensions in the 4 to 50 kilometer range. An urban scale station would be useful for assessing trends in citywide air quality and the effectiveness of larger scale air pollution control strategies.

Regional Scale—Measurements from these stations would characterize air quality levels over areas having dimensions of 50 to hundreds of kilometers. This large scale of representativeness, rarely used in Pb monitoring, would be most applicable to sparsely populated areas and could provide information on background air quality and inter-regional pollutant transport.

Monitoring for ambient Pb levels is required for all major urbanized areas where Pb levels have been shown or are expected to be of concern due to the proximity of Pb point source emissions. Sources emitting five tons per year or more of actual point and fugitive Pb emissions would generally be candidates for lead ambient air monitoring. Modelling may be needed to determine if a source has the potential to exceed the quarterly lead National Ambient Air Quality Standards (NAAQS). The total number and type of stations for SLAMS are not prescribed but must be determined on a case-by-case basis. As a minimum, there must be two stations in any area where Pb concentrations currently exceed or have exceeded the Pb NAAQS during any one quarter of the most recent eight quarters. Where the Pb air quality violations are widespread or the emissions density, topography, or population locations are complex and varied, there may be a need to establish more than two Pb ambient air monitoring stations. The EPA Regional Administrator may specify more than two monitoring stations if it is found that two stations are insufficient to adequately determine if the Pb standard is being attained and maintained. The Regional

Administrator may also specify that stations be located in areas outside the boundaries of the urbanized areas.

Concerning the previously discussed required minimum of two stations, at least one of the stations must be a category (a) type station and the second may be either category (a) or (b) depending upon the extent of the point source's impact and the existence of residential neighborhoods surrounding the source. When the source is located in an area that is subject to NAMS requirements as in Section 3 of this Appendix, it is preferred that the NAMS site be used to describe the population's exposure and the second SLAMS site be used as a category (a) site. Both of these categories of stations are defined in section 3.

To locate monitoring stations, it will be necessary to obtain background information such as point source emissions inventories, climatological summaries, and local geographical characteristics. Such information should be used to identify areas that are most suitable to the particular monitoring objective and spatial scale of representativeness desired. References 9 & 10 of this appendix provide additional guidance on locating sites to meet specific urban area monitoring objectives and should be used in locating new stations or evaluating the adequacy of existing stations.

After locating each Pb station and, to the extent practicable, taking into consideration the collective impact of all Pb sources and surrounding physical characteristics of the siting area, a spatial scale of representativeness must be assigned to each station.

3. Network Design for National Air Monitoring Stations (NAMS)

For each urban area where NAMS are required, both categories of monitoring stations must be established. In the case of Pb and SO₂ if only one NAMS is needed, then category (a) must be used. The analysis and interpretation of data from NAMS should consider the distinction between these types of stations as appropriate.

3.2 Sulfur Dioxide Design Criteria for NAMS

*** The actual number and location of the NAMS must be determined by EPA Regional Offices and the State Agency, subject to the approval of EPA Headquarters, Office of Air Quality Planning and Standards (OAQPS).

3.3 Carbon Monoxide (CO) Design Criteria for NAMS

*** At the national level, EPA will not routinely require data from as many stations as are required for PM-10, and perhaps SO₂, since CO trend stations are principally needed to assess the overall air quality progress resulting from the emission controls required by the Federal motor vehicle control program (FMVCP) and other local controls.

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3.6 *Lead (Pb) Design Criteria for NAMS.*
 In order to achieve the national monitoring objective, one NAMS site must be located in one of the two cities with the greatest

population in the following ten regions of the country (the choice of which of the two metropolitan areas should have the lead NAMS requirement is made by the

Administrator or the Administrator's designee using the recommendation of the Regional Administrators or the Regional Administrators' designee):

TABLE 1.—EPA REGIONS & TWO CURRENT LARGEST MSA/CMSAs (USING 1995 CENSUS DATA)

Region (States)	Two Largest MSA/CMSAs
I (Connecticut, Massachusetts, Maine, New Hampshire, Rhode Island, Vermont)	Boston-Worcester-Lawrence CMSA, Hartford, CT MSA.
II (New Jersey, New York, Puerto Rico, U.S. Virgin Islands)	New York-Northern New Jersey-Long Island, CMSA, San Juan-Caguas-Arecibo, PR CMSA.
III (Delaware, Maryland, Pennsylvania, Virginia, West Virginia, Washington, DC)	Washington-Baltimore CMSA, Philadelphia-Wilmington-Atlantic City CMSA.
IV (Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee)	Miami-Fort Lauderdale CMSA, Atlanta, GA MSA.
V (Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin)	Chicago-Gary-Kenosha CMSA, Detroit-Ann Arbor-Flint CMSA.
VI (Arkansas, Louisiana, New Mexico, Oklahoma, Texas)	Dallas-Fort Worth CMSA, Houston-Galveston-Brazoria CMSA.
VII (Iowa, Kansas, Missouri, Nebraska)	St. Louis MSA, Kansas City MSA.
VIII (Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming)	Denver-Boulder-Greeley CMSA, Salt Lake City-Ogden MSA.
IX (American Samoa, Arizona, California, Guam, Hawaii, Nevada)	Los Angeles-Riverside-Orange County CMSA, San Francisco-Oakland-San Jose CMSA.
X (Alaska, Idaho, Oregon, Washington)	Seattle-Tacoma-Bremerton CMSA, Portland-Salem CMSA.

In addition, one NAMS site must be located in each of the MSA/CMSAs where one or more violations of the quarterly Pb NAAQS have been recorded over the previous eight quarters. If a violation of the quarterly Pb NAAQS is measured at a monitoring site outside of a MSA/CMSA, one NAMS site must be located within the county in a populated area, apart from the Pb source, to assess area wide Pb air pollution levels. These NAMS sites should represent the maximum Pb concentrations measured within the MSA/CMSA, city, or county that is not directly affected from a single Pb point source. Further, in order that on-road mobile source emissions may continue to be verified as not contributing to lead NAAQS violations, roadside ambient lead monitors should be considered as viable NAMS site candidates. A NAMS site may be a microscale or middle scale category (a) station, located adjacent to a major roadway (e.g., >30,000 ADT), or a neighborhood scale category (b) station that is located in a highly populated residential section of the MSA/CMSA or county where the traffic density is high. Data from these sites will be used to assess general conditions for large MSA/CMSAs and other populated areas as a marker for national trends, and to confirm continued attainment of the Pb NAAQS. In some cases, the MSA/CMSA subject to the latter lead NAMS requirement due to a violating point source will be the same MSA/CMSA subject to the lead NAMS requirement based upon its population. For these situations, the total minimum number of required lead NAMS is one.

6. References
- * * * * *
 - 6. Lead Guideline Document, U. S. Environmental Protection Agency, Research Triangle Park, NC. EPA-452/R-93-009.
 - 7. Air Quality Criteria for Lead. Office of Research and Development, U.S. Environmental Protection Agency, Washington, DC. EPA-600/8-83-028 aF-dF, 1986, and supplements EPA-600/8-89/049F,

- August 1990. (NTIS document numbers PB87-142378 and PB91-138420.)
- * * * * *
- 10. "Guidance for Conducting Ambient Air Monitoring for Lead Around Point Sources," Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC EPA-454/R-92-009, May 1997.
- * * * * *
- 19. National Air Pollutant Emissions Trends, 1900-1995, Office of Air Quality Planning and Standards, U. S. Environmental Protection Agency, Research Triangle Park, NC. EPA-454/R96-007, October 1996, updated annually.

6. Appendix E is amended by revising the first paragraph of section 7.1, adding a sentence at the beginning of section 7.3, revising section 7.4, and revising reference 18 in section 13 to read as follows:

Appendix E—Probe and Monitoring Path Siting Criteria for Ambient Air Quality Monitoring

- * * * * *
- 7.1 *Vertical Placement.* Optimal placement of the sampler inlet for Pb monitoring should be at breathing height level. However, practical factors such as prevention of vandalism, security, and safety precautions must also be considered when siting a Pb monitor. Given these considerations, the sampler inlet for microscale Pb monitors must be 2-7 meters above ground level. The lower limit was based on a compromise between ease of servicing the sampler and the desire to avoid unrepresentative conditions due to re-entrainment from dusty surfaces. The upper limit represents a compromise between the desire to have measurements which are most representative of population exposures and a consideration of the practical factors noted above.
- * * * * *
- 7.3. *Spacing from Roadways.* This criteria applies only to those Pb sites designed to

assess lead concentrations from mobile sources. Numerous studies have shown that ambient Pb levels near mobile sources are a function of the traffic volume and are most pronounced at ADT >30,000 within the first 15 meters on the downwind side of the roadways.

* * * * *

7.4. *Spacing from trees and other considerations.* Trees can provide surfaces for deposition or adsorption of Pb particles and obstruct normal wind flow patterns. For microscale and middle scale category (a) sites there must not be any tree(s) between the source of the Pb and the sampler. For neighborhood scale category (b) sites, the sampler should be at least 20 meters from the drip line of trees. The sampler must, however, be placed at least 10 meters from the drip line of trees which could be classified as an obstruction, i.e., the distance between the tree(s) and the sampler is less than the height that the tree protrudes above the sampler.

- * * * * *
- 13. References
- * * * * *
- 18. Air Quality Criteria for Lead. Office of Research and Development, U.S. Environmental Protection Agency, Washington, DC EPA-600/8-83-028 aF-dF, 1986, and supplements EPA-600/8-89/049F, August 1990. (NTIS document numbers PB87-142378 and PB91-138420.)
- * * * * *

7. Section 1 and section 2 b of Appendix G are revised to read as follows:

Appendix G—Uniform Air Quality Index and Daily Reporting

* * * * *

1. *General.* This appendix describes the uniform air quality index to be used by States in reporting the daily air quality index required by § 58.50.

2. Definitions.

* * * * *

b. Reporting Agency means the applicable State agency or a local air pollution control agency designated by the State, that will carry out the provisions of § 58.50.

* * * * *

[FR Doc. 99-1125 Filed 1-19-99; 8:45 am]
BILLING CODE 6600-00-P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180**

[OPP-300771; FRL 9051-0]

RIN 2070-AB78

Imidacloprid; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of imidacloprid in or on Legume Vegetables (Crop Group 8, 40 CFR 180.41(c)(6)) and Strawberries. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on legumes and strawberries. This regulation establishes maximum permissible levels for residues of imidacloprid in these food commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerances will expire and are revoked on June 30, 2000.

DATES: This regulation is effective January 20, 1999. Objections and requests for hearings must be received by EPA on or before March 22, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP-300771], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP-300771], must also be submitted to: Public Information and Records Integrity Branch, Information Resources

and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/8.1 or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP-300771]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Andrea Beard, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308-9356; e-mail: beard.andrea@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 348a(e) and (l)(6), is establishing a tolerance for residues of the insecticide imidacloprid (1-[6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine), in or on legume vegetables and strawberries, at 1.0 and 0.1 part per million (ppm), respectively. These tolerances will expire and are revoked on 6/30/00. EPA will publish a document in the Federal Register to remove the revoked tolerances from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104-170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities

under a new section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996) (FRL-5572-9).

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue."

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that "emergency conditions exist which require such exemption." This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerance to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

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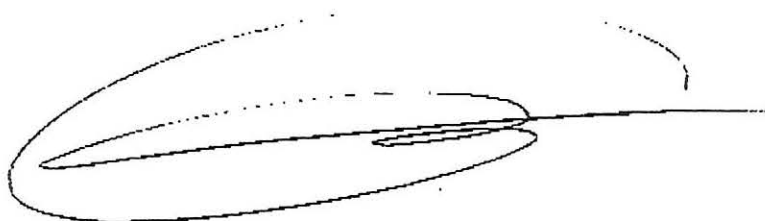
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POSICIÓN COMÚN (CE) Nº 57/98

aprobada por el Consejo el 24 de septiembre de 1998

con vistas a la adopción de la Directiva 98/.../CE del Consejo, de ..., relativa a los valores límite de dióxido de azufre, dióxido de nitrógeno y óxidos de nitrógeno, partículas y plomo en el aire ambiente

(98/C 360/04)

EL CONSEJO DE LA UNIÓN EUROPEA

Visto el Tratado constitutivo de la Comunidad Europea y, en particular, el apartado 1 de su artículo 130 S,

Vista la propuesta de la Comisión⁽¹⁾,

Visto el dictamen del Comité Económico y Social⁽²⁾,

De conformidad con el procedimiento establecido en el artículo 189 C del Tratado⁽³⁾,

- (1) Considerando que, basándose en los principios consagrados en el artículo 130 R del Tratado, el Programa comunitario de política y actuación en materia de medio ambiente y desarrollo sostenible (Quinto Programa de acción en materia de medio ambiente)⁽⁴⁾ prevé en particular la modificación de la legislación vigente sobre contaminantes atmosféricos; que el mencionado Programa recomienda fijar objetivos a largo plazo en relación con la calidad del aire;
- (2) Considerando que el artículo 129 del Tratado establece que las exigencias en materia de protección de la salud deben constituir un componente de las demás políticas de la Comunidad; que la letra o) del artículo 3 del Tratado establece que la acción de la Comunidad debe implicar una contribución al logro de un alto nivel de protección de la salud;
- (3) Considerando que el apartado 5 del artículo 4 de la Directiva 96/62/CE del Consejo, de 27 de septiembre de 1996, sobre evaluación y gestión de la calidad del aire ambiente⁽⁵⁾ dispone que el Consejo adopte la legislación contemplada en el apartado 1 y las normas contempladas en los apartados 3 y 4 de dicho artículo;

⁽¹⁾ DO C 9 de 14.1.1998, p. 6.

⁽²⁾ Dictamen emitido el 29 de abril de 1998 (DO C 214 de 10.7.1998, p. 1).

⁽³⁾ Dictamen del Parlamento Europeo de 13 de mayo de 1998 (no publicado aún en el Diario Oficial), Posición común del Consejo de 24 de septiembre de 1998 y Decisión del Parlamento Europeo de ... (no publicada aún en el Diario Oficial).

⁽⁴⁾ DO C 138 de 17.5.1993, p. 3.

⁽⁵⁾ DO L 296 de 21.11.1996, p. 33.

- (4) Considerando que los valores límite establecidos por la presente Directiva constituyen requisitos mínimos; que, de conformidad con el artículo 130 T del Tratado, los Estados miembros podrán mantener y adoptar valores límite más exigentes; que, en particular, se podrán establecer disposiciones más exigentes para proteger la salud de categorías de la población especialmente vulnerables, como los niños y los pacientes hospitalizados; que los Estados miembros podrán establecer valores límite que deban alcanzarse en una fecha anterior a la establecida en la presente Directiva;
- (5) Considerando que es preciso proteger los ecosistemas frente a los efectos adversos del dióxido de azufre; que es preciso proteger la vegetación de los efectos perjudiciales de los óxidos de nitrógeno;
- (6) Considerando que los distintos tipos de partículas pueden tener distintos efectos nocivos en la salud de las personas; que se ha demostrado que los riesgos que supone para la salud de las personas la exposición a partículas producidas por las actividades humanas son superiores a los riesgos que lleva aparejados la exposición a partículas de origen natural en el aire ambiente;
- (7) Considerando que la Directiva 96/62/CE requiere la elaboración de planes de acción para las zonas en las que las concentraciones de uno o más contaminantes superan el valor o valores límite incrementados por el margen de exceso tolerado temporal para que se cumpla el valor o valores límite en la fecha especificada; que esos planes de acción y demás estrategias de reducción, cuando guarden relación con las partículas, deben tener por objeto reducir las concentraciones de partículas finas, como parte de la reducción global de las concentraciones de partículas;
- (8) Considerando que la Directiva 96/62/CE establece que los valores límite numéricos y los umbrales de alerta deben basarse en los resultados de la labor realizada por grupos científicos internacionales que se ocupan de esta materia; que la Comisión debe tener en cuenta los datos más recientes sobre epidemiología y medio ambiente obtenidos en los trabajos de investigación científica, así como los últimos avances en métodos de medición, para examinar los elementos en los que se basan los valores límite y los umbrales de alerta;

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- (9) Considerando que, para facilitar la revisión de la presente Directiva en el año 2003, la Comisión y los Estados miembros deberían considerar la posibilidad de alentar la investigación sobre los efectos de los contaminantes a los que la Directiva se refiere, es decir, el dióxido de azufre, el dióxido de nitrógeno y los óxidos de nitrógeno, las partículas y el plomo;
- (10) Considerando que unas técnicas normalizadas de medición que permiten obtener resultados precisos y unos criterios comunes para la ubicación de los centros de medición son elementos importantes para la evaluación de la calidad del aire ambiente con vistas a obtener datos comparables en toda la Comunidad;
- (11) Considerando que, de conformidad con el apartado 1 del artículo 12 de la Directiva 96/62/CE, las modificaciones necesarias para la adaptación al progreso científico y técnico sólo podrán referirse a los criterios y técnicas de evaluación de las concentraciones de dióxido de azufre, dióxido de nitrógeno y óxidos de nitrógeno, partículas y plomo o a las disposiciones detalladas para la transmisión de información a la Comisión, y que dichas modificaciones no deberán suponer una modificación, directa o indirecta, de los valores límite ni de los umbrales de alerta;
- (12) Considerando que la población debe poder acceder con rapidez a información actualizada sobre las concentraciones de dióxido de azufre, dióxido de nitrógeno y óxidos de nitrógeno, partículas y plomo en el aire ambiente,

HA ADOPTADO LA PRESENTE DIRECTIVA:

Artículo 1

Objetivos

La presente Directiva tiene por objeto:

- establecer valores límite y, en su caso, umbrales de alerta con respecto a las concentraciones de dióxido de azufre, dióxido de nitrógeno y óxidos de nitrógeno, partículas y plomo en el aire ambiente para evitar, prevenir o reducir los efectos nocivos para la salud humana y para el medio ambiente en su conjunto,
 - evaluar, a partir de métodos y criterios comunes, las concentraciones de dióxido de azufre, dióxido de nitrógeno y óxidos de nitrógeno, partículas y plomo en el aire ambiente,
 - obtener información adecuada sobre las concentraciones de dióxido de azufre, dióxido de nitrógeno y óxidos de nitrógeno, partículas y plomo en el aire ambiente y velar por que la población tenga conocimiento de la misma,
- mantener la calidad del aire ambiente cuando ésta sea buena y mejorarla en los demás casos con respecto al dióxido de azufre, el dióxido de nitrógeno y los óxidos de nitrógeno, las partículas y el plomo.

Artículo 2

Definiciones

A efectos de la presente Directiva se entenderá por:

- 1) «aire ambiente»: el aire exterior de la troposfera, excluidos los lugares de trabajo;
- 2) «contaminante»: cualquier sustancia introducida directa o indirectamente por el hombre en el aire ambiente que pueda tener efectos nocivos sobre la salud humana o el medio ambiente en su conjunto;
- 3) «nivel»: la concentración de un contaminante en el aire ambiente o su depósito en superficies en un momento determinado;
- 4) «evaluación»: cualquier método utilizado para medir, calcular, predecir o estimar el nivel de un contaminante en el aire ambiente;
- 5) «valor límite»: un nivel fijado basándose en conocimientos científicos, con el fin de evitar, prevenir o reducir los efectos nocivos para la salud humana y para el medio ambiente en su conjunto, que debe alcanzarse en un plazo determinado y no superarse una vez alcanzado;
- 6) «umbral de alerta»: un nivel a partir del cual una exposición de breve duración supone un riesgo para la salud humana y a partir del cual los Estados miembros deberán tomar medidas inmediatas como establece la Directiva 96/62/CE;
- 7) «límite de exceso tolerado»: el porcentaje del valor límite en el que éste puede sobrepasarse con arreglo a las condiciones establecidas en la Directiva 96/62/CE;
- 8) «zona»: la porción de su respectivo territorio delimitada por los Estados miembros;
- 9) «aglomeración»: un área que se caracteriza por una concentración de población de más de 250 000 habitantes o, cuando la concentración de población es inferior o igual a 250 000 habitantes, por una densidad de habitantes por km² que justifica que los Estados miembros evalúen y controlen la calidad del aire ambiente;
- 10) «óxidos de nitrógeno»: la suma, en partes por 1 000 millones, de óxido nítrico y dióxido de nitrógeno expresada como dióxido de nitrógeno, en mg/m³.

- 11) «PM₁₀»: las partículas que pasan a través de un cabezal de tamaño selectivo con una eficiencia de corte del 50% para un diámetro aerodinámico de 10 µm;
- 12) «PM_{2,5}»: las partículas que pasan a través de un cabezal de tamaño selectivo con una eficiencia de corte del 50% para un diámetro aerodinámico de 2,5 µm;
- 13) «umbral de evaluación superior»: el nivel especificado en el anexo V, por debajo del cual puede utilizarse una combinación de mediciones y técnicas de modelización para evaluar la calidad del aire ambiente, con arreglo al apartado 3 del artículo 6 de la Directiva 96/62/CE;
- 14) «umbral de evaluación inferior»: el nivel especificado en el anexo V, por debajo del cual es posible limitarse al empleo de técnicas de modelización o de estimación objetiva para evaluar la calidad del aire ambiente, con arreglo al apartado 4 del artículo 6 de la Directiva 96/62/CE;
- 15) «fenómeno natural»: las erupciones volcánicas, las actividades sísmicas, los incendios indeseados de zonas silvestres, los fuertes vientos y la resuspensión atmosférica o el transporte de partículas naturales procedentes de regiones áridas;
- 16) «mediciones fijas»: las mediciones realizadas con arreglo a lo dispuesto en el apartado 5 del artículo 6 de la Directiva 96/62/CE.

Artículo 3

Dióxido de azufre

1. Los Estados miembros adoptarán las medidas necesarias para que las concentraciones de dióxido de azufre en el aire ambiente, evaluadas con arreglo al artículo 7, no excedan de los valores límite fijados en el punto I del anexo I a partir de las fechas que en el mismo se indican.

Los márgenes de tolerancia que se especifican en el punto I del anexo I se aplicarán de conformidad con el artículo 8 de la Directiva 96/62/CE.

2. El umbral de alerta para las concentraciones de dióxido de azufre en el aire ambiente figura en el punto II del anexo I.

3. Para ayudar a la Comisión a preparar el informe que cita el artículo 10, los Estados miembros almacenarán, cuando proceda hasta el 31 de diciembre de 2003, las concentraciones de dióxido de azufre registradas como promedio de períodos de diez minutos en algunas estaciones seleccionadas por los Estados miembros como representativas de la calidad del aire en las áreas habitadas próximas a las fuentes y en las que se midan las concentraciones horarias. Al mismo tiempo que se sumi-

nistran los datos sobre las concentraciones horarias de conformidad con lo dispuesto en el punto I del artículo 11 de la Directiva 96/62/CE, los Estados miembros comunicarán a la Comisión, respecto a las estaciones de medición seleccionadas, el número de las concentraciones promediadas durante períodos de diez minutos que excedan los 500 µg/m³, el número de días dentro del año civil en que ocurrió tal hecho, el número de días simultáneos en que las concentraciones horarias de dióxido de azufre excedieron también los 350 µg/m³ y la máxima concentración registrada en los períodos de 10 minutos.

4. Los Estados miembros podrán designar zonas o aglomeraciones dentro de las que se rebasen los valores límite de dióxido de azufre a que se refiere el punto I del anexo I debido a concentraciones de dióxido de azufre en el aire ambiente producidas por fuentes naturales. Los Estados miembros remitirán a la Comisión una lista de cualesquiera de esas zonas o aglomeraciones junto con la información sobre las concentraciones y fuentes de dióxido de azufre dentro las mismas. Cuando informen a la Comisión de conformidad con lo dispuesto en el apartado I del artículo 11 de la Directiva 96/62/CE, los Estados miembros facilitarán la justificación necesaria para demostrar que los rebasamientos se deben a fuentes naturales.

Dentro de dichas zonas o aglomeraciones los Estados miembros estarán obligados a ejecutar planes de actuación de conformidad con el apartado 3 del artículo 8 de la Directiva 96/62/CE sólo cuando se rebasen los valores límite a que se refiere el punto I del anexo I debido a emisiones antropogénicas.

Artículo 4

Dióxido de nitrógeno y óxidos de nitrógeno

1. Los Estados miembros adoptarán las medidas necesarias para que las concentraciones de dióxido de nitrógeno y, en su caso, las concentraciones de óxidos de nitrógeno en el aire ambiente, evaluadas con arreglo al artículo 7, no excedan de los valores límite fijados en el punto I del anexo II a partir de las fechas indicadas.

Los márgenes de tolerancia que se especifican en el punto I del anexo II se aplicarán de conformidad con el artículo 8 de la Directiva 96/62/CE.

2. El umbral de alerta para las concentraciones de dióxido de nitrógeno en el aire ambiente figura en el punto II del anexo II.

Artículo 5

Partículas

1. Los Estados miembros adoptarán las medidas necesarias para que las concentraciones de PM₁₀ en el aire

ambiente, evaluadas con arreglo al artículo 7, no excedan de los valores límite indicados en el punto I del anexo III a partir de las fechas indicadas.

Los márgenes de tolerancia que se especifican en el punto I del anexo III se aplicarán de conformidad con el artículo 8 de la Directiva 96/62/CE.

2. Los Estados miembros garantizarán que se instalen y exploren estaciones de medición que proporcionen datos sobre las concentraciones de $PM_{2.5}$. El número y situación de las estaciones en que se mida $PM_{2.5}$ serán elegidos por los Estados miembros para que sean representativos de las concentraciones de $PM_{2.5}$ en esos Estados miembros. Cuando sea posible, los puntos de muestreo se instalarán en el mismo lugar que los puntos de muestreo de PM_{10} .

Los Estados miembros presentarán cada año a la Comisión, a más tardar nueve meses después de finalizar el año, la media aritmética, la mediana, el percentil 98 y la concentración máxima calculados a partir de las mediciones de $PM_{2.5}$ durante veinticuatro horas en ese año. El percentil 98 se calculará con arreglo al procedimiento establecido en el punto 4 del anexo I de la Decisión 97/101/CE del Consejo, de 27 de enero de 1997, por la que se establece un intercambio recíproco de información y datos de las redes y estaciones aisladas de medición de la contaminación atmosférica en los Estados miembros⁽¹⁾.

3. Los planes de actuación correspondientes a las partículas PM_{10} preparados con arreglo al artículo 8 de la Directiva 96/62/CE y las estrategias generales de reducción de las concentraciones de PM_{10} tendrán por objeto reducir al mismo tiempo las concentraciones de $PM_{2.5}$.

4. Cuando se superen los valores límite de PM_{10} a que se refiere el punto I del anexo III debido a concentraciones de PM_{10} en el aire ambiente producidas por fenómenos naturales, que supongan concentraciones considerablemente superiores a los niveles de fondo procedentes de fuentes naturales, los Estados miembros informarán de ello a la Comisión de conformidad con el punto 1 del artículo 11 de la Directiva 96/62/CE y facilitarán la justificación necesaria para demostrar que dichos rebasamientos se deben a fenómenos naturales. En estos casos, los Estados miembros tendrán la obligación de ejecutar planes de actuación con arreglo al apartado 3 del artículo 8 de la Directiva 96/62/CE sólo cuando se rebasen los valores límite a que se refiere el punto I del anexo III por causas que no sean tales fenómenos naturales.

5. Los Estados miembros podrán designar zonas o aglomeraciones en las cuales se rebasen los valores límite de PM_{10} a que se refiere el punto I del anexo III a causa de la existencia de concentraciones de PM_{10} en el aire ambiente debidas a la resuspensión de partículas a raíz del vertido invernal de arena para el mantenimiento de

las carreteras. Los Estados miembros remitirán a la Comisión una lista de las posibles zonas o aglomeraciones de este tipo, junto con información sobre las concentraciones y fuentes de PM_{10} existentes en las mismas. Cuando informen a la Comisión con arreglo a lo dispuesto en el punto 1 del artículo 11 de la Directiva 96/62/CE, los Estados miembros suministrarán la información necesaria para demostrar que los rebasamientos se deben a la mencionada resuspensión de partículas y que se han adoptado medidas razonables para reducir las concentraciones.

Dentro de dichas zonas o aglomeraciones, los Estados miembros sólo estarán obligados a aplicar planes de actuación de conformidad con lo dispuesto en el apartado 3 del artículo 8 de la Directiva 96/62/CE en caso de que se rebasen los valores límite a que se refiere el punto I del anexo III debido a la presencia de niveles de PM_{10} distintos de los que se deriven del vertido invernal de arena para el mantenimiento de las carreteras.

Artículo 6

Plomo

Los Estados miembros adoptarán las medidas necesarias para que las concentraciones de plomo en el aire ambiente, evaluadas con arreglo al artículo 7, no excedan de los valores límite fijados en el punto I del anexo IV a partir de las fechas indicadas.

Los márgenes de tolerancia que se especifican en el punto I del anexo IV se aplicarán de conformidad con el artículo 8 de la Directiva 96/62/CE.

Artículo 7

Evaluación de las concentraciones

1. En el punto I del anexo V figuran los umbrales superior e inferior de evaluación correspondientes al dióxido de azufre, el dióxido de nitrógeno y los óxidos de nitrógeno, las partículas y el plomo a los fines del artículo 6 de la Directiva 96/62/CE.

La clasificación de cada zona o aglomeración a efectos de lo dispuesto en el artículo 6 de la mencionada Directiva se revisará por lo menos cada cinco años con arreglo al procedimiento establecido en el punto II del anexo V. Esa revisión podrá tener lugar antes de lo establecido si se producen cambios significativos en las actividades que pueden tener una incidencia sobre las concentraciones en el ambiente de dióxido de azufre, dióxido de nitrógeno o, cuando proceda, óxidos de nitrógeno, partículas o plomo.

2. En el anexo VI se establecen los criterios que deben aplicarse para determinar el emplazamiento de los puntos

⁽¹⁾ DO L 35 de 5.2.1997, p. 14

de muestreo con vistas a la medición de dióxido de azufre, dióxido de nitrógeno y óxidos de nitrógeno, partículas y plomo. El anexo VII establece el número mínimo de puntos de muestreo para las mediciones fijas de concentraciones de cada contaminante pertinente.

3. En las zonas o aglomeraciones en las que la información proporcionada por las estaciones de medición fijas se complete con información procedente de otras fuentes, tales como inventarios de emisiones, métodos de medición indicativa y modelos de la calidad del aire, el número de estaciones de medición fijas que deben instalarse y la resolución espacial de las demás técnicas deben ser suficientes para que sea posible determinar las concentraciones de los contaminantes atmosféricos establecidos con arreglo al punto I del anexo VI y al punto I del anexo VIII.

4. En las zonas y aglomeraciones en que no se requieran mediciones podrán utilizarse técnicas de modelización o de estimación objetivas.

5. En los puntos I a III del anexo IX figuran los métodos de referencia para el análisis de dióxido de azufre, dióxido de nitrógeno y óxidos de nitrógeno y para el muestreo y el análisis de plomo.

El método de referencia para el muestreo y la medición de PM_{10} figura en el punto IV del anexo IX.

El proyecto provisional de método de referencia para el muestreo y la medición de $PM_{2,5}$ figura en el punto V del anexo IX.

El punto VI del anexo IX establece las técnicas de referencia para la modelización de la calidad del aire.

6. La fecha en que los Estados miembros informarán a la Comisión acerca de los métodos empleados para la evaluación preliminar de la calidad del aire con arreglo a la letra d) del punto 1 del artículo 11 de la Directiva 96/62/CE será de dieciocho meses después de la entrada en vigor de la Directiva.

7. Las modificaciones que sean necesarias para adaptar las disposiciones del presente artículo y de los anexos V a IX al progreso científico y técnico se adoptarán con arreglo al procedimiento establecido en el artículo 12 de la Directiva 96/62/CE.

Artículo 8

Información al público

1. Los Estados miembros garantizarán que periódicamente se ponga a disposición del público así como de organizaciones apropiadas, tales como organizaciones de

medio ambiente y de consumidores, organizaciones que representen los intereses de poblaciones sensibles y otras organizaciones apropiadas pertinentes, información actualizada sobre las concentraciones de dióxido de azufre, dióxido de nitrógeno y óxidos de nitrógeno, partículas y plomo en el aire ambiente a través, por ejemplo, de la radio y la televisión, la prensa, pantallas de información o servicios de redes informáticas.

La información sobre las concentraciones de dióxido de azufre, dióxido de nitrógeno y óxidos de nitrógeno, partículas y plomo en el aire ambiente se actualizará, como mínimo, cada día, y cada hora por lo que respecta a los valores horarios de dióxido de azufre y de dióxido de nitrógeno, en caso de que resulte viable. La información sobre concentraciones de plomo en el aire ambiente se actualizará en base trimestral.

La información indicará, al menos, todos los casos en que las concentraciones superen los valores límite y los umbrales de alerta durante los periodos de promedio especificados en los anexos I a IV. También incluirá una breve evaluación en relación con los valores límite y con los umbrales de alerta, así como información adecuada en relación con las repercusiones para la salud.

2. Cuando los Estados miembros pongan a disposición de la población planes o programas con arreglo al apartado 3 del artículo 8 de la Directiva 96/62/CE, los pondrán también a disposición de las organizaciones contempladas en el apartado 1.

3. Cuando se rebase el umbral de alerta citado en el punto II de los anexos I y II, los detalles difundidos al público con arreglo al artículo 10 de la Directiva 96/62/CE incluirán, como mínimo, los puntos citados en la lista del punto III de los anexos I y II.

4. La información que se proporcione al público y a las organizaciones en virtud de lo dispuesto en los anteriores apartados 1 y 3 deberá ser clara, comprensible y accesible.

Artículo 9

Derogaciones y disposiciones transitorias

1. La Directiva 90/779/CEE del Consejo, de 15 de julio de 1990, relativa a los valores límite y a los valores guía de calidad atmosférica para el anhídrido sulfuroso y las partículas en suspensión⁽¹⁾ quedará derogada con efectos a partir del [...], excepto el artículo 1, el apartado 1 del artículo 2, el apartado 1 del artículo 3, los artículos 9, 15 y 16 y los anexos I, III b y IV, que quedarán derogados con efectos a partir del 1 de enero de 2005.

(1) Veinticuatro meses después de la entrada en vigor de la presente Directiva.

(2) DO L 229 de 30.3.1990, p. 30.

2. La Directiva 82/884/CEE del Consejo, de 3 de diciembre de 1982, relativa al valor límite para el plomo contenido en la atmósfera⁽¹⁾ quedará derogada con efectos a partir del [...] ^(*), excepto los artículos 1 y 2, el apartado 1 del artículo 3 y los artículos 7, 12 y 13, que quedarán derogados con efectos a partir del 1 de enero de 2005.

3. La Directiva 85/203/CEE del Consejo, de 7 de marzo de 1985, relativa a las normas de calidad del aire para el dióxido de nitrógeno⁽²⁾ quedará derogada con efectos a partir del [...] ^(*), excepto el primer guión del apartado 1 del artículo 1, el apartado 2 del artículo 1, el primer guión del artículo 2, el apartado 1 del artículo 3, los artículos 5, 9, 15 y 16 y el anexo I, que quedarán derogados con efectos a partir del 1 de enero de 2010.

4. A partir del [...] ^(*), los Estados miembros utilizarán estaciones de medición y otros métodos de evaluación de la calidad del aire de conformidad con la presente Directiva para evaluar las concentraciones de dióxido de azufre, dióxido de nitrógeno y plomo en el aire ambiente con objeto de obtener los datos destinados a demostrar que se cumplen los valores límite establecidos en las Directivas 80/779/CEE, 82/884/CEE y 85/203/CEE hasta el momento en que dejen de aplicarse los valores límite establecidos en esas Directivas.

5. A partir del [...] ^(*), los Estados miembros podrán utilizar estaciones de medición y otros métodos de evaluación de la calidad del aire de conformidad con la presente Directiva por lo que respecta al PM₁₀ para analizar las concentraciones de partículas en suspensión a fin de demostrar el cumplimiento de los valores límite establecidos en el anexo IV de la Directiva 80/779/CEE, si bien, para demostrar dicho cumplimiento, los datos así recogidos deberán multiplicarse por un factor de 1,2.

6. Los Estados miembros informarán a la Comisión de todo rebasamiento de los valores límite establecidos por las Directivas 80/779/CEE, 82/884/CEE y 85/203/CEE, así como de los valores registrados, las razones de cada caso registrado y las medidas adoptadas para evitar cualquier posible repetición; dicha información se comunicará a la Comisión anualmente durante los nueve primeros meses de cada año de conformidad con el procedimiento establecido en el artículo 11 de la Directiva 96/62/CEE, y hasta tanto dejen de aplicarse los valores límite pertinentes.

7. En las zonas en las que el Estado miembro afectado considere necesario limitar o prevenir un incremento previsible de la contaminación causada por dióxido de azufre, dióxido de nitrógeno o partículas en suspensión,

podrá seguir utilizando los valores orientativos para la protección de los ecosistemas que figuran en el anexo II de la Directiva 80/779/CEE y en el anexo II de la Directiva 85/203/CEE.

Artículo 10

Informe y revisión

A más tardar el 31 de diciembre de 2003 la Comisión presentará al Parlamento Europeo y al Consejo un informe sobre la aplicación de la presente Directiva y, en particular, sobre los resultados de las investigaciones científicas más recientes acerca de los efectos en la salud humana y en los ecosistemas de la exposición al dióxido de azufre, dióxido de nitrógeno y óxidos de nitrógeno, las distintas fracciones de partículas y el plomo, así como sobre la evolución de la tecnología, incluidos los avances realizados en relación con los métodos de medición y de otro tipo de análisis de las concentraciones de partículas en el aire ambiente y de la deposición de las partículas y del plomo en superficies.

Con vistas a mantener un elevado nivel de protección de la salud humana y del medio ambiente y teniendo en cuenta la experiencia obtenida gracias a la aplicación de la Directiva en los Estados miembros, incluidas, en particular, las condiciones en que, de conformidad con lo dispuesto en el anexo VI, se hayan llevado a cabo las mediciones, dicho informe se acompañará, cuando proceda, de propuestas de modificación de la presente Directiva. En especial, la Comisión estudiará los valores límite de PM₁₀ para la segunda fase con miras a hacerlos obligatorios, y considerará la posibilidad de confirmar o modificar los valores límite para la segunda fase y, si procede, para la primera. Además, la Comisión concederá especial atención al establecimiento de valores límite para PM_{2,5} o para diferentes fracciones de partículas, según resulte adecuado, y estudiará el valor límite anual para la protección de la salud humana para el dióxido de nitrógeno y presentará una propuesta que confirme o modifique dicho valor. También examinará el valor límite horario para el dióxido de nitrógeno a la luz de las directrices de la Organización Mundial de la Salud y considerará si el valor límite debe ser confirmado o modificado.

Artículo 11

Sanciones

Los Estados miembros determinarán el régimen de sanciones aplicable a las infracciones de las disposiciones nacionales adoptadas en aplicación de la presente Directiva. Las sanciones serán eficaces, proporcionadas y disuasorias.

(*) Veinticuatro meses después de la entrada en vigor de la presente Directiva.

(1) DO L 378 de 31.12.1982, p. 15.

(2) DO L 87 de 27.3.1985, p. 1.

Artículo 12**Aplicación**

1. Los Estados miembros adoptarán las disposiciones legales, reglamentarias y administrativas necesarias para cumplir la presente Directiva a más tardar [...](*). Informarán inmediatamente de ello a la Comisión.

Cuando los Estados miembros adopten dichas disposiciones, éstas harán referencia a la presente Directiva o irán acompañadas de dicha referencia en su publicación oficial. Los Estados miembros establecerán las modalidades de la mencionada referencia.

2. Los Estados miembros comunicarán a la Comisión el texto de las disposiciones de Derecho interno que adopten en el ámbito regulado por la presente Directiva.

Artículo 13**Entrada en vigor**

La presente Directiva entrará en vigor el vigésimo día siguiente al de su publicación en el *Diario Oficial de las Comunidades Europeas*.

Artículo 14**Destinatarios**

Los destinatarios de la presente Directiva serán los Estados miembros.

Hecho en ...

Por el Consejo
El Presidente

(* Veinticuatro meses después de la entrada en vigor de la presente Directiva.